

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION</b>	:	<b>CIVIL ACTION</b>
	:	
	:	
	:	
	:	<b>MDL No. 3094</b>
	:	<b>24-md-3094</b>
<b>THIS DOCUMENT RELATES TO:</b>	:	
	:	<b>HON. KAREN SPENCER MARSTON</b>
<b><i>ALL ACTIONS/ALL CASES</i></b>	:	

**MEMORANDUM**

**Marston, J.** **August 15, 2025**

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This MDL involves personal injury actions stemming from the use of glucagon-like peptide-1 (GLP-1) receptor agonists and GLP-1/glucose-dependent insulintropic polypeptide (GIP) dual receptor agonists (collectively, “GLP-1 RAs”) manufactured by the Novo Nordisk Defendants (“Novo”)<sup>1</sup> and the Eli Lilly Defendants (“Lilly”)<sup>2</sup>. (*See generally* Doc. Nos. 1, 294.) Eight GLP-1 RA medications are at issue: Ozempic, Wegovy, Rybelsus, Victoza and Saxenda, which are manufactured by Novo; and Trulicity, Mounjaro, and Zepbound, which are manufactured by Lilly.<sup>3</sup>

As of the date of this Memorandum, there are more than 2600 cases included in the MDL, but members of Plaintiffs’ leadership team have suggested that this number will increase (*see* June 10, 2024 Hr’g Tr. at 16:18–23 (“And there are known to us, meaning co-lead counsel, approximately 5,000 Novo-only cases under investigation; about 1,200 Lilly-only cases; and then about 1,400 combined Novo and Lilly.”); Feb. 24, 2025 Hr’g Tr. at 8:1–12 (cautiously

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<sup>1</sup> The Novo Nordisk Defendants are Novo Nordisk A/S and Novo Nordisk Inc. (*See* Doc. No. 294 at ¶¶ 15–17.)

<sup>2</sup> The Eli Lilly Defendants are Eli Lilly and Company and Lilly USA, LLC. (*See* Doc. No. 294 at ¶¶ 20–21.)

<sup>3</sup> Although the Judicial Panel on Multidistrict Litigation (“JPML”) has not identified Victoza and Zepbound by name when transferring cases to be part of this MDL, the parties agree that they are properly included in the Master Complaint and considered by the Court now. (*See* Apr. 4, 2025 Hr’g Tr. at 6:2–7:1.) As the Court explains later in this Memorandum, Victoza, like Saxenda, is merely a brand name for the drug liraglutide, and Zepbound, like Mounjaro, is merely a brand name for the drug, tirzepatide. Because Saxenda and Mounjaro are part of this MDL, Victoza and Zepbound are as well.

asserting that “I don’t think we see anything that would expect the prediction to change”); *but see* July 29, 2025 Hr’g Tr. at 49:11–18 (“[I]n Morgan & Morgan’s view, I don’t think there will be 10,000 cases in the MDL.”)). Although the alleged drug, dosage, and precise injury vary by Plaintiff, there are many commonalities. Notably, each Plaintiff claims they were prescribed one or more of the eight identified medications for the treatment of type 2 diabetes and/or chronic weight management and that as a result, they suffered gastrointestinal symptoms and/or injuries, such as “debilitating cyclical vomiting,” gastroparesis, ileus, intestinal obstruction, gallbladder injury, vitamin deficiency, Wernicke’s Encephalopathy, ischemic bowel, and necrotizing pancreatitis. (Doc. No. 294 at ¶¶ 4, 13, 41.)

Plaintiffs’ Co-Lead Counsel have filed a Master Long Form Complaint and Demand for Jury Trial (the “Master Complaint”), which seeks to broadly include the factual scenarios and potential claims common to every Plaintiff. (Doc. No. 294.) Once the pleadings are closed, each Plaintiff will file a short form complaint, which incorporates by reference those portions of the Master Complaint applicable to their situation, identifies which counts they are asserting, and adds additional allegations and counts as appropriate. (*Id.* at 5–6 & n.2; *see also* Doc. No. 387-2 (proposed short form complaint).) Currently before the Court is Defendants’ joint motion to dismiss the Master Complaint. (Doc. No. 329.) Plaintiffs’ Co-Lead Counsel have filed a brief in opposition to that motion. (Doc. No. 364.) Defendants filed a reply brief (Doc. No. 392), and the Court held oral argument on the motion on April 21, 2025. For the reasons discussed below, the motion is granted in part and denied in part.

## **I. BACKGROUND**

The Master Complaint is more than 240 pages and 850 paragraphs long. (*See generally* Doc. No. 294.) In short, it alleges a concerted, decades-long effort by Defendants to change the

medical landscape and embed GLP-1 RAs into the American cultural conscience. Defendants deny these allegations, but in deciding the motion to dismiss, the Court must take them as true.

#### **A. An Overview of GLP-1 RAs**

GLP-1 RAs mimic the naturally occurring hormone GLP-1, which is produced in the brain and intestinal walls of animals and regulates blood sugar, appetite, and digestion. (*Id.* at ¶ 29.) In 1993, researchers analyzing the venom of gila monsters discovered a glucagon peptide called exendin-4, which activates GLP-1 receptors, allowing gila monsters to maintain stable blood sugar levels despite going months without eating. (*Id.* at ¶ 30.) Building on this discovery, scientists with Lilly and Amylin Pharmaceuticals created a synthetic form of exendin-4, called exenatide, which came to market to treat type 2 diabetes in 2005 under the brand name Byetta. (*Id.* at ¶ 31.) At the same time, Novo was developing a drug called liraglutide, which was showing promise curbing eating in rats. (*Id.* at ¶ 32.) Liraglutide came to market in 2010 under the brand name Victoza and was later reintroduced under the brand name Saxenda. (*Id.*)

In the decades since exenatide and liraglutide were developed, multiple other GLP-1 RAs have been brought to market. (*Id.* at ¶ 33.) As relevant here, Novo manufactures semaglutide under the brand names Ozempic, Wegovy, and Rybelsus, with the differences between each medication being the mechanism of administration, the approved used, and the allowed dosage.<sup>4</sup> Ozempic was first approved by FDA in 2017, Rybelsus in 2019, and Wegovy in 2021. (*See id.* at ¶¶ 109, 114, 120.) Similarly, Lilly manufactures dulaglutide under the

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<sup>4</sup> Ozempic and Wegovy are administered by injection. (*Id.* at ¶¶ 38–39.) Rybelsus, by contrast, is taken as a once daily tablet. (*Id.* at ¶ 38.) For the most part, doses range between 0.25 and 2 milligrams per week. (*Id.* at ¶ 40.) However, Wegovy is approved up to a maximum dose of 2.4 milligrams per week. (*Id.*)

brand name Trulicity and tirzepatide under the brand names Mounjaro and Zepbound. (*Id.* at ¶ 33.) Again, the main differences between Mounjaro and Zepbound are the approved use and the allowed maximum dosage.<sup>5</sup> Trulicity was first approved by FDA in 2014, Mounjaro in 2022, and Zepbound in 2023. (*Id.* at ¶¶ 140, 145, 151.)

The FDA considers GLP-1 RAs to be a class of drugs based on “similarities in their mechanisms of action, physiologic effects, and chemical structure.” (*Id.* at ¶ 34.) Each drug “mimic[s] the activities of physiologic GLP-1” by attaching to GLP-1 receptors in the body and sending signals that trigger a sensation of satiety, stimulate the release of insulin, suppress the release of glucagon, and slow or inhibit gastric emptying and intestinal motility. (*Id.* ¶ 35.) Most GLP-1 RAs, including Ozempic, Wegovy, Rybelsus, Victoza, Trulicity, and Mounjaro, are approved to treat type 2 diabetes. (*Id.* at ¶ 37.) That said, some medications, including Wegovy, Saxenda, and Zepbound, are approved to treat chronic weight management (i.e., obesity). (*Id.*) In addition, Ozempic, Rybelsus, Victoza, and Trulicity are approved for cardiovascular risk reduction, and Zepbound is approved to treat sleep apnea in patients with obesity. All eight medications are approved for adult use, but Victoza and Trulicity are also approved for use by children as young as 10 years old, and Wegovy and Saxenda are approved for use by children as young as 12 years old.

## **B. Defendants’ Marketing Campaigns**

Plaintiffs claim Defendants have downplayed the dangerous side effects of their GLP-1 RAs, overplayed the potential benefits to be gained from taking them, and encouraged their off-label use through a comprehensive marketing campaign focused on medicalizing obesity and

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<sup>5</sup> The maximum approved dose for both Zepbound and Mounjaro is 15 milligrams per week. (*Id.* at ¶ 40; Apr. 21, 2025 Hr’g Tr. at 123:23–124:4.)

pushing the image of these medications as “miracle” weight loss drugs. (*See id.* at ¶ 276 (“Novo sought to fundamentally change the paradigm that doctors and insurers applied to weight-loss treatments.”); *id.* at ¶ 301 (“Lilly’s Chief Customer Officer acknowledged . . . that there was a ‘lot of work required to medicalize obesity.’”); *id.* at ¶¶ 436–37 (“Defendants purposefully downplayed, understated and ignored the health hazards and risks associated with using GLP-1 RAs.”).)

#### 1. Novo’s Campaign

In the United States in the “early-2000s, there was substantial dispute as to whether obesity should be classified as a disease rather than a behavioral issue.” (*Id.* at ¶ 277; *see also id.* at ¶ 295 (representing that this is “one of the most polarizing topics in modern medicine”).) Defendants, through advocacy organizations, supported recognition of obesity as a disease. (*Id.* at ¶ 277.) Around this time, Novo in particular “began intentionally targeting the obesity market.” (*Id.* at ¶ 278.) For example, in 2012, it identified “establish presence in obesity” as a strategic focus area in its annual investment report. (*Id.*) And in the years that followed, Novo repeatedly stated in its annual reports to investors and in various presentations that it “intend[ed] to change the perception of obesity and the way it’s treated,” i.e., “to advocate that it must be classified as a disease, covered by insurance, and treated with its weight loss drugs.” (*Id.* at ¶ 282; *see also id.* at ¶ 307.)

In 2013, the obesity debate came to a head when the American Medical Association (“AMA”)—against the recommendation of its Committee on Science and Public Health—classified obesity as a “disease state that requires treatment and prevention.” (*Id.* at ¶¶ 277, 293.) One year later, Novo relaunched liraglutide under the brand name Saxenda and marketed it as the first GLP-1 RA weight loss drug. (*Id.* at ¶ 279.) Three years later, Novo launched a

second GLP-1 RA, semaglutide, which has since entered the market under the names Ozempic, Wegovy, and Rybelsus. (*Id.* at ¶¶ 280–81; *see also id.* at ¶¶ 109, 114, 120.) Although Saxenda and Wegovy are the only medications approved for chronic weight management, Plaintiffs allege that Novo has marketed all its GLP-1 RAs as “obesity drug[s].” (*Id.* at ¶ 281.) They claim Novo engaged in a “multiprong approach” focused on “creating and expanding the market for its weight-loss drugs” that targeted physicians, consumers, and insurers. (*Id.* at ¶ 283.)

First, Plaintiffs allege Novo worked to “target physicians and change prescribing behavior” by undercutting “the well-established health guidance that diet and exercise are key to healthy weight loss . . . and, in its place, pushing a pharmaceutical intervention as the only treatment option that will be successful.” (*Id.* at ¶ 284; *see also id.* ¶ 296 (“Novo began working to change the medical consensus as it relates to obesity treatment including advocating for pharmaceutical treatment for obesity and minimizing lifestyle interventions.”).) To get this message across, Novo “flooded the medical community with money in an effort to change the medical consensus as it relates to treating obesity,” by, among other things, making “direct payments to physicians,” supporting “advocacy organizations” (including the Obesity Action Coalition and the American Board of Obesity Medicine), “funding research, promoting articles in well-respected journals, and controlling key opinion leaders.” (*Id.* at ¶ 283; *accord id.* at ¶ 309.) For example, Plaintiffs allege that between 2018 and 2023, Novo paid physicians around \$153 million in general payments (e.g., marketing, consulting, travel, food and beverage). (*Id.* at ¶ 312.) And they claim Dr. Fatima Cody Stanford, an obesity specialist who promoted the safety and efficacy of GLP-1 RAs on “60 Minutes” and “Oprah,” has “received significant payments from Novo.” (*Id.* at ¶ 319.)

Second, Novo targeted consumers with “buzzy social media campaigns, emotional impact videos, and top-notch celebrity endorsements.” (*Id.* at ¶¶ 285, 306.) Plaintiffs allege that “Novo invested billions in marketing Ozempic and its other GLP-1 RAs to push Ozempic into the cultural zeitgeist, creating an image as a miracle drug and driving patients to pressure their doctors to prescribe a ‘weight-loss’ drug.” (*Id.* at ¶ 285; *see also id.* at ¶ 373 (alleging that between July 2018 and the end of 2023, “Novo spent approximately \$884 [m]illion on television advertising in the United States to promote Ozempic and later, its other semaglutide, Wegovy”).) Like in its campaigns to physicians, Novo pushed the narrative that lifestyle changes often aren’t enough and more (i.e., a prescription) is needed to “overcome obesity” and realize “long term health.” (*Id.* at ¶¶ 298–99.) In addition, Novo “routinely promoted Ozempic” as “contributing to weight loss even though” it “was not approved for that indication.” (*Id.* at ¶ 308; *see also id.* at ¶ 409 (alleging that “Novo’s Ozempic website has consistently touted weight loss”).) For example, on July 30, 2018, Novo launched its first Ozempic television advertisement, which noted that “you may lose weight” and that adults taking Ozempic to treat their type 2 diabetes “lost on average up to 14 pounds.” (*Id.* at ¶¶ 372, 408.)

Third, Novo worked to overcome the “substantial hurdles” presented by the drugs’ “high cost,” which served as a barrier to access for many consumers. (*Id.* at ¶ 286.) Plaintiffs allege that Novo partnered with telehealth companies to make it easier for consumers to receive a prescription. (*Id.* at ¶¶ 286, 306, 416–20 (alleging that “the telehealth providers that Novo directly and indirectly partnered with and/or promotes account for approximately half of all weight loss prescriptions in 2022”).) And it offered some consumers “an Instant Savings Card to reduce co-pays to as low as \$25 per prescription fill for up to two years.” (*Id.* at ¶ 431.) At



the same time, Novo “engag[ed] with a broad range of coalition partners to advocate for obesity care and Medicare coverage.” (*Id.* at ¶ 305; *see also id.* at ¶ 309 (alleging Defendants “spen[t] millions of dollars lobbying for prescription drug coverage of GLP-1 RAs”).) Of note, Novo has lobbied for Congress to pass the Treat and Reduce Obesity Act, which would require Medicare to cover prescriptions approved for chronic weight management. (*Id.* at ¶ 360; *see also id.* at ¶ 361 (alleging that Novo spent \$35 million between 2012 and 2023 lobbying for the Act’s passage).)

## 2. Lilly’s Campaign

Plaintiffs claim that Lilly has engaged in a similar campaign to change the medical and cultural landscape. (*Id.* at ¶ 287.) Lilly’s dulaglutide, Trulicity, was first approved for type 2 diabetes in 2014, and its two tirzepatides, Mounjaro and Zepbound, were approved in 2022 and 2023 respectively. (*Id.* at ¶¶ 140, 145, 151.) Only Zepbound has been approved for chronic weight management.

First, Plaintiffs allege that Lilly, like Novo, has focused on “shift[ing] the conversation for people to actually start thinking about obesity as a medical condition.” (*Id.* at ¶ 288.) Among other things, it has made “direct payments to doctors, many of whom were influential in the relevant disciplines, so that they would promote the use of GLP-1 RAs,” “fund[ed] articles regarding the safety and efficacy of the GLP-1 RAs,” sent individuals to speak “at conferences regarding the safety and efficacy of GLP-1 RAs,” “influenc[ed] health care advocacy groups focused on obesity and obesity treatment” (including the Obesity Action Coalition and the American Board of Obesity Medicine), and held “continuing medical education seminars related to GLP-1 RAs.” (*Id.* at ¶¶ 309, 331–344.) For example, in 2022, Lilly spent approximately \$3.5 million purchasing physician meals while promoting Mounjaro and Trulicity. (*Id.* at ¶ 313.)

And between 2020 and 2023, Lilly paid nearly \$100,000 to Dr. Ania Jastreboff, who appeared on “Oprah” to discuss the benefits of its medications. (*Id.* at ¶ 324.)

Second, Lilly “spent vast sums of money on all forms of advertising and marketing to grow consumer demand,” including “promoting off-label use of Mounjaro” for weight loss. (*Id.* at ¶ 287.) In 2023 alone, Lilly spent more than \$1 billion marketing its diabetes and weight loss drugs, with \$139 million spent promoting Mounjaro. (*Id.* at ¶ 379.) Like Novo, Lilly targeted consumers with direct-to-consumer websites, social media marketing campaigns, and television advertisements that emphasized “obesity is a disease that requires pharmaceutical treatment.” (*Id.* at ¶ 300; *id.* at ¶ 391 (discussing Lilly’s involvement in “various unbranded online platforms” meant to “promote pharmaceutical intervention for obesity”); *id.* at ¶¶ 392, 395, 400 (discussing social media campaigns).) And it similarly advertised Mounjaro as “contributing to weight loss even though” it “was not approved for that indication.” (*Id.* at ¶ 308; *see also id.* at ¶ 414 (“Lilly repeatedly promoted weight loss on its website.”).) For example, in February 2023, Lilly advertised that “people taking Mounjaro lost up to 25 lbs.” (*Id.* at ¶ 384; *see also id.* at ¶ 415 (discussing similar television advertisements).) Similarly, since 2018, Lilly’s campaigns for Trulicity have included assertions that the medication may help consumers “lose a little weight” or “lose up to 10lbs.” (*Id.* at ¶ 380.)

Last, Plaintiffs allege that, Lilly, like Novo, has worked to lower the barrier to entry for consumers, including offering prescriptions at a discount. (*Id.* at ¶ 432.) Lilly has invested in the telehealth market, creating its own company, LillyDirect, which connects patients with independent telehealth providers to facilitate prescriptions, and once prescribed, patients can purchase Mounjaro and Zepbound directly through Lilly’s portal. (*Id.* at ¶¶ 423, 425.) Lilly has also “spent millions of dollars lobbying for changes in the law to support broader financial

support and access for obesity treatments.” (*Id.* at ¶ 287, 309, 357–69.) In May 2022, Lilly’s then-Executive Vice President and President of Diabetes and Obesity emphasized that the “main driver in the evolution of the obesity market will be access,” and in particular, Medicare “Part D coverage,” which is what the proposed “Treat and Reduce Obesity Act [is] trying to do.” (*Id.* at ¶ 303; *see also id.* at ¶ 364 (“From 2021 to August 2024, Lilly spent over \$2 [m]illion lobbying for obesity drug coverage . . . including lobbying related to the Treat & Reduce Obesity Act.”).) That same year, Lilly’s Chief Science Officer noted that because there are “limits to what Medicare w[ill] cover for obesity,” it is also important to consider “backdoors”—i.e., other approved uses for GLP-1 RAs, like sleep apnea—“to increasing usage” in patients “on the [sic] Medicare.” (*Id.* at ¶ 304.)

### 3. The Drugs’ Success

By all appearances, Defendants’ campaigns have been a success. Plaintiffs claim that Defendants’ “massive spending resulted in cultural saturation and caused Ozempic” and other GLP-1 RAs “to become [ ] household name[s] and engrained in pop culture.” (*Id.* at ¶¶ 375–76.) And the result is that “[p]eople want[ ] to use these drugs to lose weight, regardless of whether the drugs ha[ve] been approved for that purpose or not.” (*Id.* at ¶ 377; *see also id.* at ¶ 289 (alleging that in May 2024, CNN published that 1 in 8 U.S. adults has taken a GLP-1 drug).)

This has led to unprecedented profits for both Defendants. In August 2023, Novo reported that in the first six months of 2023, U.S. sales of Wegovy soared 344% to nearly \$1.7 billion and sales of Ozempic soared 50% to more than \$3.7 billion. (*Id.* at ¶ 289.) In total, between January 2021 and December 2023 prescriptions for semaglutide (Ozempic, Wegovy, and Rybelsus) soared over 442%. (*Id.*) Lilly reported similar results, with Mounjaro

“generat[ing] \$5.2 billion in 2023,” and Zepbound “pull[ing] in more than \$175 [m]illion in its first quarter on the market.” (*Id.* at ¶ 291.)

### C. Defendants’ Omissions

Plaintiffs allege that the extensive marketing campaigns conducted by both Defendants oversold the weight loss potential of the drugs and hid darker truths about their side effects. Specifically, “Defendants’ extensive multifaceted advertising, marketing and promotion of GLP-1 RAs . . . consistently highlighted and overstated the weight loss benefits of taking a GLP-1 RA while failing to disclose the risks identified with those drugs and concealing other information that would be material to any Plaintiff and their physician in weighing the risks and benefits of taking a GLP-1 RA.” (*Id.* at ¶ 588.)

#### 1. Drug Efficacy

First, Plaintiffs claim the medications are not as effective as Defendants have suggested. As noted above, each of the eight medications implicated in the Master Complaint has been approved to treat either type 2 diabetes (Ozempic, Rybelsus, Victoza, Saxenda, Trulicity, and Mounjaro) or chronic weight management (Wegovy, Saxenda, and Zepbound). Plaintiffs allege that Defendants failed to disclose, however, that for the medications approved for weight management, many patients are unlikely to see meaningful or sustainable weight loss because they quickly discontinue using the medications, do not respond to the drugs, or gain back the weight after they stop taking them. (*Id.* at 96–102.)

Among other studies, Plaintiffs reference an “issue brief” published by Blue Cross Blue Shield, which examined whether “patients prescribed [GLP-1 RAs] for weight loss are dropping out of treatment too quickly to attain the health benefits of these drugs.” (*Id.* at ¶ 97 (citing *Real-world trends in glp-1 treatment persistence and prescribing for weight management*, Blue Health Intelligence Issue Brief (2024)

([https://www.bcbs.com/media/pdf/BHI\\_Issue\\_Brief\\_GLP1\\_Trends.pdf](https://www.bcbs.com/media/pdf/BHI_Issue_Brief_GLP1_Trends.pdf).) The insurance company considered 170,000 GLP-1 RA users and concluded that 30% of patients discontinued treatment within 4 weeks, that 58% discontinued treatment within 180 days, and that patients who discontinue treatment “shortly after starting GLP-1 RA therapy are unlikely to see *any* health benefits.” (*Id.* at ¶ 97.) Plaintiffs also reference a study published by Novo in March 2021, which acknowledges that “weight loss for semaglutide [Ozempic, Wegovy, and Rybelsus] users is likely to plateau between weeks 60 and 68 and that patients who discontinue use of semaglutide gradually regained weight.” (*Id.* at ¶ 99.)

Plaintiffs claim that Defendants were on notice of these issues but “intentionally omitted” from “their labels, physician communications, marketing, website, public statements, and other public facing communications” that:

(1) the average person only loses a small percentage of their body weight while on a GLP-1 RA; (2) GLP-1 RAs are not effective for everyone; (3) patients gain the weight back when they stop taking the GLP-1 RA (i.e., patients have to stay on the drug forever); (4) the weight loss achieved while on a GLP-1 RA is not a healthy weight loss; (5) when a patient regains the weight loss achieved while on a GLP-1 RA, they are typically less healthy than when they began the medication; and (6) many people stop taking a GLP-1 RA relatively quickly because of trouble tolerating the drugs.

(*Id.* at ¶ 589.)

## 2. Harmful Side Effects

In addition to overstating the benefits of taking these medications, Plaintiffs claim Defendants have also “downplayed the chronic nature, duration and severity of gastrointestinal injuries caused by their GLP-1 RAs.” (*Id.* at ¶ 43.) They allege GLP-1 RAs can and have caused a “myriad of injuries” including:

- Cyclical vomiting,

- Gastroparesis,<sup>6</sup>
- Ileus,<sup>7</sup>
- Gastroenteritis,
- Intestinal obstruction,
- Ischemic colitis,<sup>8</sup>
- Necrotizing pancreatitis,
- Gallbladder disease,
- Micronutrient disease, which can lead to muscle wasting and Wernicke's Encephalopathy,<sup>9</sup> and
- Intraoperative aspiration.

(*See, e.g., id.* at ¶¶ 41–95.) For ease of reference, the Court refers to these injuries collectively as the “Alleged Injuries.”

Plaintiffs allege that Defendants “were on notice that there is reasonable evidence of a causal association between” their medications and the Alleged Injuries, yet Defendants failed to take appropriate steps to warn the medical community and members of the public. (*Id.* at ¶¶ 155–225, 249–56, 434; *see also id.* at ¶ 435 (“Defendants spent hundreds of millions of

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<sup>6</sup> “Gastroparesis” refers to the “slowing or halting of transit of food from the stomach to the intestines in the absence of a physical obstruction.” (*Id.* at ¶ 45.)

<sup>7</sup> “Ileus” refers to a “temporary lack of the normal muscle contractions of the intestines.” (*Id.* at ¶ 53.) When ileus occurs, the normal contract-and-relax pattern within the intestines “is slowed or stopped, preventing food, gas, and liquids from passing through the digestive tract.” (*Id.*)

<sup>8</sup> Ischemic colitis occurs when “blood flow to the colon or large intestine is diminished.” (*Id.* at ¶ 60.) The condition can lead “to obstruction or perforation of the bowel, and necrosis and infection of the affected tissue.” (*Id.*)

<sup>9</sup> Wernicke's Encephalopathy is “a life-threatening degenerative brain disorder caused by the lack of vitamin B1,” also known as thiamine, “and is characterized by mental confusion, vision problems, coma, hypothermia, low blood pressure, and ataxia (or lack of muscle coordination).” (*Id.* at ¶ 90.)

dollars to aggressively expand the market for the GLP-1 RAs while misleading users and healthcare providers about the serious dangers.”.) Plaintiffs claim Defendants failed to include appropriate warnings on product labels—including a warning about each Alleged Injury—such that the labels have been inadequate since the launch of each medication. (*Id.* at ¶¶ 463–508, 516–87, 589.) They also assert that Defendants have failed to comply with regulations that require them to investigate adverse events associated with their GLP-1 RAs, to update product labels to add and strengthen warnings, and to report all relevant safety information to the FDA. (*Id.* at ¶¶ 438–45.)

## II. PROCEDURAL HISTORY

On February 5, 2024, the JPML ruled that personal injury actions alleging gastrointestinal injuries stemming from the use of Defendants’ GLP-1 RAs were to be centralized for pretrial purposes in the Eastern District of Pennsylvania with the late Honorable Gene E.K. Pratter. (*See* Doc. No. 1.) The MDL was reassigned to the undersigned on June 6, 2025. (Doc. No. 138.) In the last year, this Court has issued numerous case management orders (“CMOs”) aimed at efficiently managing discovery and other pretrial issues, including CMOs scheduling early discovery and motion practice as to three cross-cutting issues (*see* Doc. Nos. 269, 282, 291, 316, 368), appointing the Honorable Lawrence F. Stengel (Retired) as Special Discovery Master (Doc. No. 213), and scheduling the submission of Plaintiffs’ fact sheets, the Master Complaint, and motions to dismiss the Master Complaint (*see* Doc. Nos. 188, 300).

On November 13, 2024, Plaintiffs filed the Master Complaint. It asserts 17 causes of action against each Defendant:

Count I:	Failure to Warn – Negligence
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Count II:	Failure to Warn – Strict Liability
Count III:	Breach of Express Warranty/Failure to Conform to Representations
Count IV:	Breach of Implied Warranty
Count V:	Fraudulent Concealment/Fraud by Omission
Count VI:	Fraudulent/Intentional Misrepresentation
Count VII:	Unfair Practices/Consumer Protections
Count VIII:	Negligent Misrepresentation/Marketing
Count IX:	Strict Liability Misrepresentation/Marketing
Count X:	Innocent Misrepresentation/Marketing
Count XI:	Negligent Design
Count XII:	Strict Liability Design Defect
Count XIII:	Negligence
Count XIV:	Negligent Undertaking
Count XV:	Wrongful Death
Count XVI:	Loss of Consortium
Count XVII:	Survival Action

(Doc. No. 294 at ¶¶ 615–877.) The Master Complaint also includes a prayer for relief, which requests noneconomic damages (e.g., pain and suffering), economic damages (e.g., medical expenses and lost earnings), punitive damages, pre- and post-judgment interest, expenses for medical monitoring, attorneys’ fees and costs, and such other relief as the Court deems proper. (*Id.* at p. 238–39.)

Defendants now move to dismiss twelve of those counts—Counts III through XIV—and Plaintiffs’ request for medical monitoring. (Doc. No. 329.) Defendants also move to strike



language from the preamble of the Master Complaint, which describes the pleading as administrative and non-operative. (*Id.*) Finally, they ask that the Court take judicial notice of each drug’s FDA-approved label as of November or December 2024. (Doc. No. 328.) Plaintiffs oppose both motions and the request for judicial notice. (Doc. Nos. 364, 365.) The Court held oral argument on the pending motions on April 21, 2025.

The Court addresses the request for judicial notice before turning to Defendants’ motion to strike, and finally, Defendants’ joint motion to dismiss.

### **III. REQUEST FOR JUDICIAL NOTICE**

Defendants ask the Court to take judicial notice of the FDA-approved GLP-1 RA product labels as of November or December 2024 (the “2024 Labels”). (Doc. No. 328.) Under Federal Rule of Evidence 201(b), a court “may judicially notice a fact that is not subject to reasonable dispute because it (1) is generally known within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably questioned.” Fed. R. Evid. 201(b). Under Rule 201(c), a court “(1) may take judicial notice on its own; or (2) must take judicial notice if a party requests it and the court is supplied with the necessary information.” Fed. R. Evid. 201(c).

Defendants argue that under Rule 201, “this Court may take notice of publicly available documents relating to warnings contained on FDA-approved product labels.” (Doc. No. 328 at 2.) Plaintiffs oppose the motion, arguing that the “Court should deny Defendants’ [r]equest because Defendants have not supplied the Court with ‘the necessary information’ to determine that the 2024 [Labels] are, or contain, any ‘fact that is not subject to reasonable dispute’ . . . ; and because the 2024 [Labels] are irrelevant to the issues, and the single claim for which Defendants offer them in their Motion.” (Doc. No. 365 at 5.)

The Court declines to take judicial notice of the labels at this time. Even assuming the 2024 Labels contain the type of information about which a Court may take judicial notice, notice is not appropriate here because the 2024 Labels do not alter the Court’s analysis on Defendants’ motion to dismiss. In their motion, Defendants reference the 2024 Labels in two sections. First, they reference them in their background discussion of the GLP-1 RAs (Doc. No. 329-1 at 14–16), but that same information appears in the allegations in the Master Complaint, which the Court accepts as true at this stage. So, the Court does not need to consider the 2024 Labels there. Second, Defendants reference the 2024 Labels to counter Plaintiffs’ contention that “Defendants did not disclose that patients frequently stop taking GLP-1 RAs . . . due to adverse events.” (*Id.* at 32.) Defendants argue that contrary to this assertion, the 2024 Labels “identify the percentage of patients who discontinued using the respective medication during clinical trials.” (*Id.* at 32–33.) But that argument does nothing to address the many cases in this MDL that are premised on the purchase of GLP-1 RAs *before* November or December 2024. As the Court explains below, we do not address state- or claimant-specific issues in ruling on the motion to dismiss the Master Complaint. Because we are not parsing claims to such a fine degree at this stage of the proceedings, we need not consider the 2024 Labels in deciding this issue either.

In short, the 2024 Labels do not alter the Court’s analysis of the motion to dismiss, so Defendants’ motion for judicial notice is denied. *See Al-Hasani v. Sec’y U.S. Dep’t of Homeland Sec.*, 81 F.4th 291, 301 (3d Cir. 2023) (declining to take judicial notice of the plaintiff’s judgment of divorce because although a “court opinion is the type of source whose accuracy cannot be readily questioned,” the notice of divorce was “not relevant” to the appellate court’s decision); *see also Victaulic Co. v. Tieman*, 499 F.3d 227, 236–37 (3d Cir. 2007) (“[W]e

believe that [judicial notice] should be done sparingly at the pleadings stage. Only in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case at that point.”).

#### **IV. MOTION TO STRIKE**

Next, Defendants move under Federal Rule of Civil Procedure 12(f) to strike portions of the Master Complaint’s preliminary statement. (Doc. No. 329-1 at 47–49.) Specifically, they argue that the Court should strike statements that suggest the Master Complaint is purely administrative and non-operative because such statements are incorrect and add confusion to the proceedings. (*Id.*)

##### **A. Legal Standard**

Federal Rule of Civil Procedure 12(f) states that the “court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f); *see also Great W. Life Assur. Co. v. Levithan*, 834 F. Supp. 858, 864 (E.D. Pa. 1993) (“A motion to strike under Rule 12(f) of the Federal Rules of Civil Procedure is the proper method to eliminate matters in pleadings which are found to be redundant, immaterial, impertinent or scandalous” or “to object to an insufficient defense.”). Although the “court possesses considerable discretion in disposing of a motion to strike under Rule 12(f),” *N. Penn. Transfer, Inc. v. Victaulic Co. of Am.*, 859 F. Supp. 154, 158 (E.D. Pa. 1994) (quotation marks omitted), “motions to strike are generally viewed with disfavor,” *Great W. Life Assur. Co.*, 834 F. Supp. at 864; *see also United States v. Marisol*, 725 F. Supp. 833, 836 (M.D. Pa. 1989) (“[M]otions to strike are often viewed with disfavor because of their potential to be used as a dilatory tactic.”). Indeed, a motion to strike “is a drastic remedy to be resorted to only when required for the purposes of justice.” *N. Penn. Transfer, Inc.*, 859 F. Supp. at 158 (quotation marks omitted).

## B. Analysis

In the Master Complaint, Plaintiffs include a preliminary statement, which describes the Master Complaint as “an administrative method to set forth common facts and potential claims which individual Plaintiffs . . . may assert against Defendants in this litigation.” (Doc. No. 294 at 5.) Plaintiffs then state that the Master Complaint “is not intended as the operative pleading for purposes of judgment and appeal, and is not intended to merge or consolidate, for any purposes, the separate claims of the Plaintiffs herein.” (*Id.* at 5–6.) Defendants ask the Court to strike this language and order that “[a]ny amended complaint should clarify that it is the Master and Short Form Complaints, in combination, that are operative for purposes of judgment and appeal.” (Doc. No. 329-1 at 47–48.) Defendants argue that striking the challenged language is appropriate because “Plaintiffs’ current pleading threatens to create inefficiency and confusion in this coordinated proceeding.” (*Id.* at 48.) Specifically, it will “undermine the Court’s ability to dismiss claims with any finality” and ignores the fact that the Master Complaint “sets forth the primary claims that Plaintiffs may bring in their Short Form Complaints and [the] factual basis for these claims.” (*Id.* at 49.)

Plaintiffs oppose the motion to strike, arguing that the Master Complaint can only be either “a consolidated complaint (where the individual cases are merged into one),” or “an administrative complaint (where the cases keep their separate identity).” (Doc. No. 364 at 19.) Because “Defendants agree with Plaintiffs that no individual cases are ‘merged or consolidated’” (Doc. No. 329-1 at 48 n.11), Plaintiffs reason that the Master Complaint must be an administrative complaint (Doc. No. 364 at 19–21).

On April 10, 2025, while the motion and response were pending, the parties submitted a proposed short form complaint and an enabling order. (Doc. No. 387.) The proposed enabling

order clarifies that “[f]or each action in this MDL, the Master Complaint together with the Short Form Complaint shall be deemed the Plaintiff’s operative Complaint,” and it incorporates the parties’ agreement that the Master Complaint “is not intended to consolidate or merge Plaintiffs’ claims.” (Doc. No. 387-1 at 1–2.) Although this would seem to address Defendants’ arguments, their reply brief, which was filed four days later, continues to request “confirmation that the Master and Short Form Complaints constitute the operative individual complaints for purposes of pleading, judgment, and appeal, as explained in the recently submitted Proposed Case Management Order.” (Doc. No. 392 at 32.)

The Court declines to grant the motion to strike. “Cases consolidated for MDL pretrial proceedings ordinarily retain their separate identities.” *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 (2015). All parties concede that is the case here. In such cases, parties may nevertheless “elect to file a ‘master complaint’ and a corresponding ‘consolidated answer.’” *Id.* at 413 n.3; *see also In re Refrigerant Compressors Antitrust Litig.* (“*In re Refrigerant*”), 731 F.3d 586, 590–92 (6th Cir. 2013) (recognizing that a master complaint that “reflects all of [the MDL plaintiffs’] allegations” represents a “common solution” to the threat to “submerge the [MDL] transferee district court in paper”). These master pleadings may be viewed as either “merging the discrete actions for the duration of the MDL pretrial proceedings,” or representing “an administrative summary of the claims brought by all the plaintiffs” without merger. *Gelboim*, 574 U.S. at 413 n.3 (quoting *In re Refrigerant*, 736 F.3d at 590–92). In *In re Refrigerant*, the Sixth Circuit noted that “[t]o ward off confusion, lawyers might do well to make plain what they have in mind when they use the label ‘master complaint.’” 731 F.3d at 591. Here, Plaintiffs’ preliminary statement does precisely that—it clarifies that the Master Complaint is not, on its own, an operative pleading that consolidates the individual actions

brought in this MDL. Instead, it is an administrative device, and, as all parties agree, in each individual case, the “Master Complaint *together with the Short Form Complaint* shall be deemed the Plaintiff’s operative Complaint.” (Doc. No. 387-1 at 1.)<sup>10</sup>

Accordingly, the motion to strike is denied.

## V. MOTION TO DISMISS

That leaves Defendants’ motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

### A. Legal Standard

Rule 12(b)(6) allows for dismissal of a claim for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). As relevant here, Federal Rules of Civil Procedure 8(a) and 9(b) provide the framework for determining whether Plaintiffs have sufficiently stated claims upon which relief can be granted.

Rule 8(a) governs most of Plaintiffs’ claims. It provides that for every claim, the complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” *In re Westinghouse Secs. Litig.*, 90 F.3d 696, 702 (3d Cir. 1996) (quoting Fed. Ri. Civ. P. 8(a)). Under this standard, a plaintiff does not need to include “detailed factual allegations,” but they must provide “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quotation marks omitted). In other words, the complaint must “contain sufficient factual

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<sup>10</sup> The administrative nature of the Master Complaint does not impair this Court’s ability to consider the pending motion to dismiss. *See, e.g., In re Zimmer*, MDL No. 2272, Master Docket No. 11 C 5468, 2012 WL 3582708, at \*4 (N.D. Ill. Aug. 16, 2012) (“Where defendants bring a motion to dismiss that raises issues common to all plaintiffs, however, the administrative nature of a Master Complaint does not necessarily preclude 12(b)(6) motion practices. . . . Consequently, the court will consider Defendants’ motion to dismiss to the limited extent that it challenges the sufficiency of the factual allegations common to all Plaintiffs.”).

matter, accepted as true,” for the court to infer that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted).

Rule 9(b), not Rule 8(a), applies to claims sounding in fraud. Under that Rule, when “alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Courts have described this standard as requiring a plaintiff to allege “all of the essential facts that would accompany ‘the first paragraph of any newspaper story’—that is, the ‘who, what, when, where and how’ of the events at issue.” *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (*In re Burlington*, 114 F.3d at 1422). “The purpose of Rule 9(b) is to provide a defendant with notice of the precise misconduct with which he or she is charged and to prevent false or unsubstantiated charges.” *Whitaker v. Herr Foods, Inc.*, 198 F. Supp. 3d 476, 485 (E.D. Pa. 2016) (quotation marks omitted).

To determine whether Rule 8 or Rule 9 governs Plaintiffs’ claims, we apply the law as interpreted by the Third Circuit. *See In re Asbestos Prods. Liab. Litig. (No. VI)*, 611 F. App’x 86, 89 (3d Cir. 2015) (“Because pleading rules are procedural in nature, the transferee court must apply federal law as interpreted by the court of the district where the transferee court sits.” (quotation marks omitted)). In this Circuit, courts look to the underlying factual bases of a claim to determine which standard applies: when a claim, however named, is grounded in allegations of negligence, Rule 8 governs; when it is grounded in allegations of fraud (i.e., intentional, knowing, or reckless misrepresentations or omissions), even if fraud is not a necessary element of the claim, the heightened requirements of Rule 9(b) apply. *In re Allergan*, 537 F. Supp. 3d at 734; *see also In re Westinghouse Secs. Litig.*, 90 F.3d at 717 n.20 (finding it was “legal error” for the district court to apply the heightened Rule 9(b) standard to the

plaintiffs’ claims without first finding that “plaintiffs’ claims sounded in fraud” or providing “some analysis explaining why Rule 9(b) should apply when [the claim] does not sound in fraud”); *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App’x 82, 85 n.3 (3d Cir. 2015) (“[A]ll of Plaintiffs’ claims alleging fraudulent activity—i.e., Plaintiffs’ claims for intentional and negligent misrepresentation, unjust enrichment and an injunction—must be pled with sufficient particularity under Rule 9(b).”).

## **B. Analysis**

Defendants move to dismiss Counts III through XIV of the Master Complaint. (Doc. No. 329.) Their arguments can be broken down into eight buckets. First, Defendants argue that Plaintiffs’ express warranty claims (Count III) fail because generalized statements that a medicine is “safe” or “effective” do not create an express warranty. Second, Defendants argue that Plaintiffs’ implied warranty claims (Count IV) fail because many courts reject such claims in product liability cases and of those which recognize such claims, Plaintiffs have not identified all the elements for each claim. Third, Defendants argue that Plaintiffs’ fraud and misrepresentation claims (Counts V, VI and VIII through X) fail because Plaintiffs have not identified actionable misstatements or omissions by either Defendant. Fourth, Defendants argue Plaintiffs’ design defect claims (Count XI and XII) fail because they are preempted and Plaintiffs have not pleaded facts to support such claims. Fifth, Defendants argue that Plaintiffs’ claims for general negligence (Count XIII) should be dismissed as redundant and inadequate because they merely repackage Plaintiffs’ other negligence-based claims. Sixth, Defendants argue that Plaintiffs’ negligent undertaking claims (Count XIV) fail because such claims are inapplicable in the prescription drug context, Plaintiffs have not pleaded the elements for such claims, and Plaintiffs are erroneously trying to plead around the learned intermediary doctrine.



Seventh, in addition to these count-specific arguments, Defendants also argue that Plaintiffs should be required to specifically plead their statutory claims. Finally, Defendants seek dismissal of Plaintiffs' request for medical monitoring relief. The Court addresses each argument in turn.

1. Breach of Express Warranty (Count III)

To begin, Defendants move to dismiss Plaintiffs' claims for breach of express warranty (Count III). "In products liability law, express warranties are the seller's affirmative assertions made in connection to a sales transaction that the sold product has certain characteristics of quality, construction, performance capability, durability, or safety." *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.* ("In re Valsartan"), MDL No. 2875 (RBK-JS), 2021 WL 222776, at \*9 (D.N.J. Jan. 22, 2021). All jurisdictions<sup>11</sup> except Louisiana have adopted the Uniform Commercial Code ("UCC") § 2-313, which relates to express warranties.<sup>12</sup> *See In re Cook Med., Inc.*, No. 1:14-ml-02570-RLY-TAB, 2024 WL 5088858, at \*4 n.3 (S.D. Ind. Mar. 19, 2024). Section 2-313 states, in relevant part, that "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain

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<sup>11</sup> As the transferee court for many of the cases in this consolidated action, the Court applies the state law that would have applied to the individual cases had they not been transferred for consolidation. *See In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8<sup>th</sup> Cir. 1996)). However, the Court is not addressing nuances of state law at this stage of the litigation. Instead, in addressing Defendants' motion to dismiss, we focus on Defendants' argument that dismissal of a given claim is warranted *regardless* of the relevant jurisdiction (e.g., Plaintiffs have not satisfied federal pleading standards as to a common element).

<sup>12</sup> Although Louisiana has not adopted § 2-313, it recognizes a claim for express warranty that, like § 2-313, requires an affirmative representation by the defendant: "To maintain a claim for nonconformity of express warranty, Plaintiff must allege that '(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue.'" *Johnson v. Johnson & Johnson*, CIVIL ACTION NO: 23-5539, 2024 WL 3202336, at \*2 (E.D. La. June 27, 2024) (quoting *Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5<sup>th</sup> Cir. 2002)).

creates an express warranty that the goods shall conform to the affirmation or promise.” UCC § 2-313(1); *see also In re Valsartan*, 2021 WL 222776, at \*9 (reading § 2-313 as requiring that a plaintiff plead three elements to state a claim for breach of express warranty: (1) the seller made an assertion about a product, to which the product did not conform, (2) but which nonetheless became part of the basis of the bargain, and (3) the buyer bought the product from the seller or was a third party beneficiary of the warranty”). As this definition suggests, “[a]n express warranty springs from a seller’s words or other form of communication rather than from any inherent characteristic of the product itself.” *In re Valsartan*, 2021 WL 222776, at \*9; *see also In re Cook Med. Inc.*, 2024 WL 5088858, at \*4 (“Plaintiffs concede that the substantive law in every jurisdiction requires some ‘affirmation of fact or promise.’”).

Defendants argue that Plaintiffs’ express warranty claims fail under this standard for three reasons: (1) “as the Third Circuit has found, the label on a prescription medication contains a number of statements, as required by FDA, that preclude finding ‘safe and effective’ to be an express warranty”; (2) “statements of opinion, including statements like ‘safe and effective,’ do not constitute express warranties”; and (3) “the failure to make a statement cannot be an express warranty.” (Doc. No. 329-1 at 18.) Plaintiffs concede the third point and confirm that they “do not base their breach of express warranty on Defendants’ omissions, but rather their affirmative representations as to the safety of the drugs” through “various outlets to patients, healthcare providers, and the public regarding the safety of their drugs.” (Doc. No. 364 at 28.) Accordingly, the Court focuses on Defendants first two arguments, addressing each in turn.

*First*, Defendants, relying on the Third Circuit’s opinion in *In re Avandia*, argue that “as a matter of law,” a plaintiff cannot “state a claim for breach of express warranty that challenges

a medication label’s representation that it was ‘safe and effective,’ where that phrase was accompanied by the ‘contraindications, risk factors, and potential side effects’ that must appear in any FDA-approved label.” (Doc. No. 329-1 at 19 (quoting *In re Avandia*, 588 F. App’x 171, 174 (3d Cir. 2014)).) Defendants overstate *In re Avandia*’s holding. In *In re Avandia*, the plaintiff’s express warranty claim was based on a single statement from an FDA-approved drug label that a given dose “has been shown to be safe and effective in clinical studies.” 588 F. App’x at 175. In dismissing the plaintiff’s claim, the court emphasized that “FDA regulations required [the defendant] to disclose the highest dose for which safety and efficacy of [the medication] had been established in clinical trials.” *Id.* The statement did not claim the drug “will be safe and effective in every case for every consumer,” nor could it “be read to make that claim when considering the entirety of the [the drug] label,” which disclosed “contraindications, risk factors, and possible side effects of the drug.” *Id.* at 175–76. In reaching its conclusion, the Third Circuit distinguished cases where drug manufacturers made “unqualified promises or affirmations” regarding a drug’s safety or made “more substantial representations than” the single statement at issue. *Id.* at 176–78.

Unlike in *In re Avandia*, here, the allegations in the Master Complaint go beyond generalized statements in the product labels that the GLP-1 RAs are “safe and effective.” Plaintiffs allege that Defendants, through their product labels, expressly represented to “Plaintiffs and Plaintiffs’ prescribing physicians that their GLP-1 RA Products were safe as an adjunct to diet and exercise to improve glycemic control and to reduce cardiovascular risks in adults with type 2 diabetes mellitus, and/or to aid in chronic weight management.” (Doc. No. 294 at ¶¶ 686–87.) They then allege that contrary to these assertions of safety, the “GLP-1 RA Products were unreasonably dangerous because of their increased risks of” causing the Alleged

Injuries. (*Id.* at ¶ 691; *see also id.* at ¶ 468 (alleging that Novo’s labels included “vague references” to injuries that “provided no notice of the magnitude of these conditions effectively downplaying the risks” and “inaccurately suggest[ing] these conditions will decrease over time and downplay[ing] the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death”); *id.* at ¶¶ 471–75 (same but for Lilly’s labels); *id.* at ¶ 695 (“[T]he GLP-1 RA Products did not conform to Defendants’ express representations because the GLP-1 RA Products were not safe” for their intended uses, “in that the drugs have reasonable evidence of a causal association with increased risks of” each Alleged Injury.).)

Plaintiffs also claim that Defendants—and scientists and celebrities hired by Defendants—represented that the medications are safe and effective *for chronic weight management* even though many of the drugs have not been approved for that purpose and the literature cited by Plaintiffs indicates that the weight loss effects are significantly overstated. (*See, e.g.*, Doc. No. 294 at ¶ 372 (Novo advertising that adults taking Ozempic “may lose weight” and that “adults lost on average up to 12 pounds”); *id.* at ¶ 380 (Lilly advertising that “taking Trulicity can help you ‘lose up to 10lbs’”); *id.* at ¶ 409 (alleging that “Novo’s Ozempic website has consistently touted weight loss” and quoting numerous representations between 2018 and 2023); *id.* at ¶ 414 (same but for Lilly’s website).) These specific representations go beyond the bald assertions of safety and efficacy with which other courts have raised concern.<sup>13</sup>

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<sup>13</sup> *Compare In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) (“[A]sserting that a product is “safe and effective” is not sufficiently clear to create an express warranty.”), and *In re Cook Med., Inc.*, 2024 WL 5088858, at \*4 (dismissing express warranty claims because the master complaint’s allegations that defendants “expressly warranted and represented in their marketing materials . . . that the filters ‘were safe, well-tolerated and fit for their intended purpose’ are conclusory . . . . Plaintiffs have not stated any actual terms of the alleged warranty or identified the particular ‘marketing materials’ or specific statements from the IFUs that they claim constitute any alleged warranties” (collecting cases)), and *House v. Bristol-Myers Squibb Co.*, CIVIL ACTION NO.

Defendants argue that these allegations are insufficient because Plaintiffs are “trying to assert in some generalized fashion that by taking a multi-pronged approach to the marketing around GLP-1 RAs that somehow creates a warranty.” (Apr. 21, 2025 Hr’g Tr. at 11:13–19; *see also id.* at 11:20–24 (arguing that Plaintiffs “generally cite to the influence that defendants have on the prescribing population, but, again, point to no specific representations”); *id.* at 102:6–12 (arguing that “[e]xpress warranty is not about volume. It’s about the specificity of what the promise is. You need to point to a specific warranty type promise and explain why that was not fulfilled”).) But as noted above, Plaintiffs identify specific assertions regarding safety and efficacy within the context of their broader framework describing Plaintiffs’ multipronged approach. That is sufficient to survive dismissal at this early stage of the litigation. *See Knipe*, 583 F. Supp. 2d at 625–26 (“As detailed above, Plaintiffs have produced sufficient evidence that GSK made various representations or affirmations of fact . . . regarding

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3:15-CV-00894-JHM, 2017 WL 55876, at \*6 (W.D. Ky. Jan. 4, 2017) (“[A] determination that a drug is safe and effective—a determination which is made by the FDA as part of its new drug approval process—is not, on its own, sufficient to create an express warranty.”), and *Center City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193, 211 n.4 (E.D. Pa. 2017) (questioning whether an express warranty claim based on representations of “safety and suitability” was “legally untenable” given the Third Circuit’s ruling in *In re Avandia*), with *Johnson v. Eisai, Inc.*, 590 F. Supp. 3d 1053, 1064 (N.D. Ohio 2022) (“Plaintiffs have done more than simply state that Defendants represented that Belviq was ‘safe and effective’ when it was not. Plaintiffs’ Complaint alleges that Defendants, through labeling, Belviq’s patient information sheets, and Defendants’ sales representatives, warranted to Mrs. Johnson and Dr. Bobouynik that Belviq was safe and effective *to use as an adjunct for chronic weight management* and that Belviq’s effectiveness outweighed any potential dangers and/or risks. . . . Plaintiffs allege that Belviq did not conform to these warranties because it neither was effective as a weight loss adjunct nor safe. . . . This provides sufficient factual allegations to plead a breach of express warranty.” (emphasis added)); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625 (E.D. Pa. 2008) (refusing to dismiss breach of express warranty claims at summary judgment where the plaintiff “produced sufficient evidence that GSK made various representations or affirmations of fact . . . regarding the safety and efficacy of Paxil *in children*,” which was an off-label use of the medication (emphasis added)), and *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceeding (“In re TRT”)*, Case No. 14 C 1748, MDL No. 2545, 2018 WL 4030586, at \*7 (N.D. Ill. Aug. 23, 2018) (denying motion for summary judgment on express warranty claim where the plaintiff put forth evidence that a sales representative visited his doctor on multiple occasions and provided materials encouraging prescription of the drug at issue as safe and effective for “age related hypogonadism,” an off-label use).

the safety and efficacy of Paxil in children. These representations were made in various articles, conferences, and journals presented to the medical community. Plaintiffs further provide proof that Paxil did not conform with these representations, since pediatric use of Paxil has been directly linked with an increased risk of suicidality.”); *Simonet v. SmithKline Beecham Corp.*, 506 F. Supp. 2d 77, 89 (D.P.R. 2007) (allowing breach of express warranty claim brought under the law of Puerto Rico to proceed here the plaintiff alleged that “GSK represented, in package inserts, prescribing information, the PDR, and other marketing literature distributed to physicians, patients, and the general public that PaxilCR is of merchantable quality, fit, effective, safe, and otherwise not injurious to the health and well-being of patients.”); *see also*, e.g., *Palmieri v. Intervet Inc.*, Civil Action No. 19-cv-22024, 2021 WL 2205854, at \*9 (D.N.J. June 1, 2021) (finding *In re Avandia* inapplicable where the defendant’s representations on its packaging, advertisements, and website “indicate that [the medication] is generally safe, save for a few ‘non-serious’ side effects,” which were contrary to the “adverse neurological reactions” allegedly suffered by the plaintiffs).

*Second*, Defendants argue that Count III should be dismissed because any representation that a given GLP-1 RA was “safe and effective” for its intended purpose was an “opinion or commendation” which “does not create a warranty.” (Doc. No. 329-1 at 19–20.) Section 2-313 of the UCC clarifies that although a seller may make an express warranty without using “formal words such as ‘warrant’ or ‘guarantee,’” a warranty is not created by a “statement purporting to be merely the seller’s opinion or commendation of the goods.” *Id.* § 2-313(2); *cf. Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993) (“Puffery is an exaggeration or overstatement expressed in broad, vague, and commendatory language. . . . Puffery is distinguishable from

misdescriptions or false representations of specific characteristics of a product. As such, it is not actionable.”).

Defendants argue that their statements about each medication’s safety and efficacy are just the type of “opinion[s] or commendation[s]” from which no warranty can arise. Although it may be true that some of Defendants’ assertions of safety and efficacy are ultimately not actionable under § 2-313, the Court cannot find that *every* representation alleged in the Master Complaint is mere puffery. As detailed above, Plaintiffs allege that Defendants made numerous specific assertions about the safety and efficacy of their GLP-1 RAs, including representations that the medications were safe and effective for weight loss despite knowing that the drugs were likely to cause the Alleged Injuries and were unlikely to lead to significant, long-lasting weight loss. *See Johnson*, 2024 WL 3202336, at \*2 (finding the defendants’ advertisements included “representations that Defendants’ baby powder ‘possesses specified characteristics or qualities,’ i.e., safety and purity,” which “go beyond a ‘general opinion’ or ‘general praise’ that a product is safe and effective” (citation omitted)); *Daley v. McNeil Consumer Prods. Co.*, 164 F. Supp. 2d 367, 377 (S.D.N.Y. 2001) (“Unlike statements that a product is ‘of high quality,’ or ‘most dependable,’ the operator’s assurance that Lactaid ‘could not cause a reaction’ goes directly to its character and quality.” (citations omitted)).

Plaintiffs’ allegations are far more specific than the “vague, subjective opinion[s]” which have been foreclosed by other courts. *Cf. Yachera v. Westminster Pharms., LLC*, 477 F. Supp. 3d 1251, 1266 (M.D. Fla. 2020) (“[V]ague, abstract statements concerning safety, dependability, and superiority are nonactionable because they are not specific enough to be falsifiable.” (quotation marks omitted)); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 355 (D. Del. 2019) (“The St. Jude sales representative’s statement that Mrs. Freed would be ‘very happy’

with the SCS device amounts to the promotion of a vague, subjective opinion. It is decidedly unclear as to what it is about the SCS device that, according to the representative, Mrs. Freed would be ‘very happy’ with. Thus, it is impossible to pin down the nature of the specific fact or promise that the representative was making to Mrs. Freed about the device and/or how the device would perform.”); *Anderson v. Bungee Intern’l Mfg. Corp.*, 44 F. Supp. 2d 534, 541 (S.D.N.Y. 1999) (“The statements that the Bungee cords are of premium or superior quality are generalized statements of salesmanship and are indistinguishable from statements that this and other courts have held to be puffery under New York law. The statements in this case are not descriptions of particular characteristics of the goods . . .”).

For those reasons, Defendants’ motion to dismiss is denied as to Count III.

## 2. Breach of Implied Warranty (Count IV)

Second, Defendants argue that Plaintiffs’ implied warranty claims (Count IV) fail because many courts reject implied warranty claims in product liability cases and of those which recognize such claims, Plaintiffs have not pleaded facts to show that the elements for each claim are met. The Court addresses each argument in turn.

Defendants begin by arguing that many states do not recognize implied warranty claims. They assert that in some jurisdictions, “implied warranty claims are subsumed by either the state’s Product Liability Act or a non-statutory strict liability cause of action,” while in others, implied warranty claims are foreclosed in the prescription context because the “role of prescribing physician . . . destroys privity or results in the claim being barred under the learned intermediary doctrine,” and finally, a third bucket of states “require privity for breach of implied warranty claims in general.” (Doc. No. 329-1 at 22–23.) This Court, like many MDL courts before us, declines to consider these state-specific issues in a motion to dismiss a master



complaint. *See, e.g., In re Hair Relaxer Mktg. Sales Practices & Prods. Liab. Litig.* (“*In re Hair Relaxer*”), 702 F. Supp. 3d 692, 705 (N.D. Ill. 2023) (“This Court agrees with the approach in other MDL cases in this district declining to rule on these state-specific issues at this stage.”); *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1964 RWS, 2009 WL 4825170, at \*2 (E.D. Mo. Dec. 11, 2009) (declining to consider the portion of the motion to dismiss which would require the court to analyze “each state’s substantive laws pertaining to particular claims” because “such case-specific rulings are neither the purpose, nor the forte, of a court presiding over a multi-district litigation” (quotation marks omitted)); *cf. In re Cook Med., Inc.*, 2024 WL 5088858, at \*4 (“The Master Complaint was filed ‘to serve the administrative functions of efficiency and economy and to present common claims and common[ ] questions of fact and law for appropriate action by this Court.’ Consequently, courts have refused to rule on a motion to dismiss ‘where doing so would require case-specific rulings to determine the sufficiency of each plaintiffs’ factual allegations.’” (cleaned up)). *But see In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.* (“*In re Allergan*”), 537 F. Supp. 3d 679, 723–751 (D.N.J. 2021) (holding, on various issues, that “Plaintiffs cannot assert” a given claim in “some jurisdictions,” and then listing the jurisdictions for which the claim is foreclosed).

The Court will, however, address Defendants’ argument that Plaintiffs have not “identif[ied] all of the elements of whichever implied warranty they are asserting” (Doc. No. 329-1 at 24), because unlike the state-specific issues discussed above, this argument addresses the adequacy of the Master Complaint’s cross-cutting allegations under Federal Rule of Civil Procedure 8, not merely whether the implied warranty claims are foreclosed as a matter of state law. Defendants argue that Plaintiffs have failed to state a claim for the implied warranty of merchantability and the implied warranty of fitness. (*Id.* at 21–22.) Plaintiffs concede they are

not asserting a claim for the implied warranty of fitness (Doc. No. 364 at 29), so the Court focuses on the implied warranty of merchantability.

Like express warranties, many states have adopted some variation of UCC § 2-314 to govern claims for breach of the implied warranty of merchantability. That section states that “a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.” UCC § 2-314(1). To be merchantable, the goods must, among other things, be at least “fit for the ordinary purposes for which such goods are used.” *Id.* § 2-314(2)(c). This standard “does not require that goods be outstanding or superior. It is only necessary that they be of reasonable quality within expected variations and fit for the ordinary purposes for which they are used.” *Sessa v. Riegle*, 427 F. Supp. 760, 769 (E.D. Pa. 1977) (discussing UCC § 2-314(2)).<sup>14</sup>

Plaintiffs argue that they “sufficiently allege that Defendants’ GLP-1 RAs were not fit for their ordinary purpose or use because they caused serious and dangerous injuries.” (Doc. No. 364 at 28; *see also id.* at 30 (“Plaintiffs have sufficiently alleged that Defendants’ GLP-1 RAs were not of merchantable quality given the severity of injuries Plaintiffs suffered for which Defendants have not disclosed the risk or the full extent of the risk.”).) Defendants respond that this argument mistakenly focuses on the allegedly undisclosed risks of taking the GLP-1 RAs, not whether the GLP-1 RAs performed as intended. The Court agrees that Plaintiffs do not claim the GLP-1 RAs were unfit for their FDA-approved pharmacological purposes, but instead, that the medications presented inherent dangers when used as intended. (*See* Apr. 21, 2025 Hr’g Tr. at 82:1–7 (Plaintiffs’ counsel conceding the medications “work for their approved

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<sup>14</sup> Defendants read § 2-314(2) as requiring Plaintiffs to allege that a “specific [GLP-1 RA is] commercially inferior to another.” (Doc. No. 329-1 at 22.) Defendants have not, however, cited any cases for this principle, nor has the Court found any cases holding as much.

purpose[s]” and clarifying that Plaintiffs’ claim is based on the assertion that the medications carry undisclosed, “dangerous side effects”).)

In some jurisdictions, similar facts have been found insufficient to state an implied warranty claim. *See In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 679 F. Supp. 3d 1314, 1323 n.5 (N.D. Fla. 2023) (finding under Alabama law that a plaintiff cannot assert an action for breach of “implied warranty of merchantability” premised on an allegation that “the product is fit for its intended use but allegedly presents other inherent dangers when used as intended”); *see also Bodie v. Purdue Pharma Co.*, 236 F. App’x 511, 523 (11th Cir. 2007) (applying Alabama law and dismissing implied warranty claim where the plaintiff alleged that the OxyContin was “unsafe” and “unreasonably dangerous” given its addictive qualities but the evidence showed that “OxyContin was, in fact, fit for its intended use as an analgesic treatment for chronic pain”); *In re Trasylol Prods. Liab. Litig.*, No. 08–MD–01928, 2010 WL 5140439, at \*13 (S.D. Fla. Feb. 16, 2020) (“Plaintiff does not argue that Trasylol was not fit for its intended use in reducing perioperative bleeding in patients undergoing cardiac surgery; Plaintiff provides no evidence suggesting that Trasylol did not successfully reduce perioperative bleeding. Instead, Plaintiff argues that Trasylol was commercially unfit because it was unreasonably dangerous (in causing renal failure, etc.). Therefore, summary judgment shall be entered in the favor of Bayer on Count III as it relates to breach of any implied warranty.”).

However, the Court cannot say that such allegations fail to state an implied warranty claim as a matter of every state’s laws. *See In re Chantix (Vareniclin) Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II)*, 735 F. Supp. 3d 352, 396–97 (S.D.N.Y. 2024) (declining to dismiss implied warranty claims in master class action complaint, rejecting as premature the manufacturer’s argument that the plaintiffs failed to allege that the drug did not “fulfill its

purpose of helping smokers quit,” and finding claims sufficient where the plaintiffs alleged that “a reasonable consumer would have expected the [medication] they purchased to have been free of contaminants and manufactured in accordance with [federal and state manufacturing requirements], in addition to her broader expectation that [the drug] perform in accordance with its clinical indications”); *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 627–28 (S.D.N.Y. 2012) (applying New York law and finding the plaintiff stated an implied warranty claim where she alleged that “Humira was not fit for its ordinary purpose” because the pharmaceutical manufacturer failed to warn that its drug for treating psoriasis caused increased risk of developing skin cancer in patients with certain medical histories); *Sellers v. Boehringer Ingelheim Pharms., Inc.*, 881 F. Supp. 2d 992, 1011 (S.D. Ill. 2012) (“The plaintiff has alleged numerous deficiencies related to Pradaxa. In addition, the plaintiff has alleged that she was hospitalized due to excessive bleeding as a result of ingesting Pradaxa. These allegations go to the issue of merchantability and are sufficient for surviving BIPI’s motion to dismiss.”); *cf. In re TRT*, No. 14 C 1748, MDL No. 2545, 2014 WL 7365872, at \*9 (N.D. Ill. Dec. 23, 2014) (collectively considering motions to dismiss 39 complaints in MDL proceeding and, “[w]ithout delving into the specifics of different states’ laws,” finding that “plaintiffs have sufficiently pled claims for breach of the implied warranty of merchantability. They plausibly allege that they believed, based on defendants’ misrepresentations and inadequate warnings, that TRTs were safe and effective for the treatment of ‘Low T’”).

Given the case law suggesting these allegations state an implied warranty claim as a matter of some states’ laws, the motion to dismiss is denied as to Count IV.<sup>15</sup>

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<sup>15</sup> Counsel for all Plaintiffs are warned, however, that they are expected to be familiar with the applicable laws and court holdings of the relevant jurisdiction, and when completing a short form complaint, they must take those laws into consideration. The Court may consider sanctions—including striking the applicable short form complaint—against any attorney or party who mindlessly “checks the

### 3. Fraud and Misrepresentation Claims (Counts V, VI, and VIII–X)

Third, Defendants argue that Plaintiffs’ fraud and misrepresentation claims (Counts V, VI, and VIII–X) fail because Plaintiffs “attempt to repackage their failure-to-warn claims into several fraud and misrepresentation claims,” without meeting the plausibility requirements of Rule 8, let alone the heightened pleading standard applicable to fraud claims under Rule 9(b). (Doc. No. 329-1 at 24–25.) The Court addresses Plaintiffs’ claims for fraudulent omission and fraudulent misrepresentation before turning to their remaining misrepresentation claims.

#### *a. Fraudulent Omission (Count V)*

To state a claim for fraudulent omission, Plaintiffs must plead that Defendants “owed them a duty to disclose” a material fact, which Defendants intentionally omitted or concealed. *In re Nat’l Hockey League Players’ Concussion Injury Litig.* (“*In re NHL*”), No. MDL 14–2551 SRN, 2015 WL 1334027, at \*9 (D. Minn. Mar. 25, 2015); *In re Hair Relaxer*, 702 F. Supp. 3d at 704 (“[A] fraudulent omission claim requires that Defendants ‘intentionally omitted or concealed a material fact that they were under a duty to disclose’ to plaintiffs.” (quoting *Wigod v. Wells Fargo Bank, N.A.*, 673 F.3d 547, 571 (7th Cir. 2012))). A fact is material if it is “the kind of fact a consumer would rely on in making her decision,” or it “would have caused her to act differently had she known of it.” *In re Hair Relaxer*, 702 F. Supp. 3d at 704. Although governed by Rule 9(b), courts have “repeatedly noted that concealment and omission cases are inherently difficult to plead with particularity because they involve events that did not occur,” and for that reason, “the ‘who, what, where, when, and how’ requirement is not as stringent for such claims.” *In re NHL*, 2015 WL 1334027, at \*10; *see also In re Hair Relaxer*, 702 F. Supp.

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box” for a claim without having a reasonable basis for asserting that claim on behalf of the relevant Plaintiff.

3d at 704 (“Plaintiffs are correct that courts consider omission-based claims under a more relaxed standard.”); *In re Valsartan*, 2021 WL 307486, at \*9 n.9 (D.N.J. Jan. 29, 2021) (recognizing “Rule 9(b) is relaxed in the context of fraud by omission”).

Plaintiffs’ concealment claims are based on two categories of omissions. First, they allege that “Defendants knew or should have known that their GLP-1 RA Products had not been adequately and/or sufficiently tested for safety” and failed to disclose that fact. (Doc. No. 294 at ¶ 732.) Second, Plaintiffs allege that Defendants knew, but failed to disclose, that “their GLP-1 RA Products were unreasonably dangerous because of the increased risk of [the Alleged Injuries].” (*Id.* at ¶ 733; *see also* Doc. No. 364 at 35 (arguing that Count V is “based on omissions—that Defendants possessed information with respect to the safety and testing of the GLP-1 RAs that they knew was material to Plaintiffs yet intentionally concealed that information”); Apr. 21, 2025 Hr’g Tr. at 83:10–15 (“What we tried to do was to lay out a bunch of places where the defendant could have made—disclosed information relating to the full safety profile of the product, could have been more up front about the true benefits and risks of the product, and chose not to.”).) As to both categories of information, Plaintiffs allege that Defendants “consciously and deliberately withheld and concealed” the information from their website, in communications with physicians, and in their promotional and marketing materials to consumers. (Doc. No. 294 at ¶¶ 735–36.)

Defendants argue that these allegations are conclusory and do not satisfy Rule 9(b), even under the more relaxed standard applicable to omissions. (Doc. No. 329-1 at 25–26.) With one exception, the Court agrees. Most of Plaintiffs’ allegations vaguely reference “communications” without providing any discussion of when and where Defendants should have included additional information about testing and safety. (*See* Doc. No. 294 at ¶ 634

(“Communications made by Defendants to Plaintiffs and Plaintiffs’ prescribing physicians were inadequate because Defendants failed to warn . . . that their GLP-1 RA Products had not been sufficiently and/or adequately tested for safety risks, including the increased risks of [the Alleged Injuries].”); *id.* at ¶ 620 (vaguely alleging Defendants “continued to market” their GLP-1 RAs to Plaintiffs “without adequate warnings”); *id.* at ¶ 627 (vaguely alleging “Defendants failed to adequately warn of [the] risks” of taking GLP-1 RAs); Apr. 21, 2025 Hr’g Tr. at 84:3–17 (arguing that “if I am in a conference and I’m speaking and I am not disclosing information. If I’m, you know, talking about advertising and I’m putting all this information out and I’m withholding information, I think that’s fraud. I think that’s fraud by omission”).)

Such vague allegations about testing and safety disclosures cannot satisfy Rule 9(b), even under the relaxed standard applied to omissions. *See Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 453 (D.N.J. 2012) (recognizing that “a plaintiff in a fraud by omission suit will not be required to specify the details of an omission as precisely as would a plaintiff asserting a false representation,” but nevertheless dismissing the plaintiff’s claim because the “complaint is lacking ‘all the essential factual background’ necessary to inform the Court of Plaintiff’s fraud claim, including what representations she relied on, if any, or where and how those representations were made, such that Plaintiff could have learned of the defect had Miele not omitted it, and whether Plaintiff would have acted differently had she known about the alleged defect”); *cf. King v. Ethicon, Inc.*, Civ. Action No. 21-17983 (FLW), 2022 WL 2341633, at \*6 (D.N.J. June 29, 2022) (dismissing fraud and fraudulent concealment claims where the plaintiff alleged that defendants falsely represented that their pharmaceutical product was “safe, effective, [and] reliable” but failed to plead “the ‘contents’ of the misrepresentations,” “the place

or manner of the misrepresentations,” and the “time when Defendants allegedly made misleading statements”).

There is one caveat to this ruling. When it comes to safety communications, Plaintiffs have specifically alleged that Defendants omitted information about the Alleged Injuries from their medications’ labels. (*See* Doc. No. 294 at ¶¶ 629–32 (alleging that “[a]t all relevant times, the labels” for the GLP-1 RAs failed to warn about “possible adverse side effects,” including the Alleged Injuries, and the “symptoms or severity of the side effects”).) For each GLP-1 RA, Plaintiffs specifically plead the type of warnings included in the medication’s labels and explain how those warnings failed to describe the risks that each medication would cause one or more of the Alleged Injuries. (*See, e.g., id.* at ¶ 463 (“At all relevant times, the ‘Warnings and Precautions’ sections of the Prescribing Information for Novo-Nordisk’s Ozempic (semaglutide) and Rybelsus (semaglutide) omitted and continue to omit any “Warnings and Precautions” concerning gastroparesis, the potential for emergent care, hospitalization, long term treatment or death.”); *id.* at ¶ 466 (similar for Wegovy); *id.* at ¶ 467 (similar for Victoza and Saxenda); *id.* at ¶ 469 (similar for Trulicity and Mounjaro); *id.* at ¶ 470 (similar for Zepbound).)

Plaintiffs also allege when Defendants knew that this additional risk information was needed. The Master Complaint references medical studies dating back to 2002, which show “prolonged cessation of motility” is tied to the use of GLP-1 RAs. (*Id.* at ¶¶ 153–61.) And Plaintiffs discuss a plethora of case reports and studies, including studies conducted by Defendants between 2008 and the present, which show an association between the use of GLP-1 RAs and the Alleged Injuries and provide support for Plaintiffs’ assertions that Defendants intentionally withheld this information. (*Id.* at ¶¶ 166–204, 434.)



Finally, Plaintiffs allege that Defendants had a duty to disclose this information because to some extent, it was exclusively in Defendants’ control and alternatively, to the extent Defendants partially disclosed any information about potential side effects in the medications’ labels, they had a duty to disclose all material information<sup>16</sup> related to likelihood that the medications would cause the Alleged Injuries. *See Jones v. CVS Health Corp.*, Civil Action No. 24-cv-1703, 2024 WL 4643514, at \*11 (E.D. Pa. Oct. 31, 2024) (“[B]ecause the Complaint pleads that Defendants shared some and concealed other material from Plaintiff Jones of Maryland and Plaintiff Manzi of Florida, Plaintiffs have sufficiently plead[ed] facts to establish a duty to disclose for their fraud claim.”); (*see also* Apr. 21, 2025 Hr’g Tr. at 109:21–110:3 (defense counsel acknowledging that the duty to disclose arises in a pure omission case only when “there’s some kind of special relationship, where there’s active concealment or *where there’s partial representations or exclusive knowledge of the information on the part of the representing party*” (emphasis added))).

The Court finds these allegations sufficiently place Defendants on notice of the nature of Plaintiffs’ fraudulent omission claims as they relate to the inclusion of information about the Alleged Injuries on the medications’ labels. *See Houston v. Bayer Healthcare Pharms., Inc.*, 16 F. Supp. 3d 1341, 1350 (N.D. Ala. 2014) (finding the plaintiff satisfied Rule 9’s particularity requirement where she alleged that pharmaceutical manufacturer failed to warn about increased risks of experiencing certain symptoms while using medical device); *In re NHL*, 2015 WL 1334027, at \*11–13 (“The Court finds that Plaintiffs have adequately alleged that the NHL

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<sup>16</sup> Defendants do not dispute that if the medications can cause the Alleged Injuries, such information would be material to consumers. *See In re Hair Relaxer*, 702 F. Supp. 3d at 704 (explaining that a fact is material if it is “the kind of fact a consumer would rely on in making her decision,” or it “would have caused her to act differently had she known of it”).

negligently or fraudulently omitted information by not taking action, signaling to players that it was alright to return to play after suffering a head injury, not properly diagnosing and treating concussions suffered by players, and implying that players were not at risk for long-term effects of their injuries and that the scientific information related to the subject was inconclusive. Accordingly, when Plaintiffs’ Master Complaint is viewed as a whole, Plaintiffs’ claims for negligent misrepresentation by omission and fraud by omission satisfy Rule 9(b).”).

Accordingly, the motion to dismiss is denied in part as to the portion of Count V that alleges fraudulent omission of information about the Alleged Injuries in the medications’ labels. The motion to dismiss is granted in part as to the remainder of Count V. Specifically, the Court finds that Plaintiffs have not sufficiently pleaded fraud by omission to the extent they try to state a claim for failure to disclose the inadequacy of testing or the potential risk of the Alleged Injuries in communications outside of the labels. Plaintiffs will, however, be given an opportunity to amend the Master Complaint and include more specific allegations as to their fraudulent omission claims.

*b. Fraudulent Misrepresentation (Count VI)*

Next, the Court turns to Plaintiffs’ fraudulent misrepresentation claim. Defendants argue that Count VI should be dismissed because Plaintiffs’ allegations “are the quintessentially vague and overly generalized allegations that courts reject as failing to meet Rule 9(b).” (Doc. No. 329-1 at 25–26.) Defendants also take issue with the “placeholder” nature of Count VI, a count which Plaintiffs have “INTENTIONALLY LEFT BLANK,” reserving “the right to amend to add fraud claims after discovery.” (*Id.*; *see also* Doc. No. 294 at 209 & n.544.) Because the Court agrees that a placeholder count of this kind is inappropriate, we need not consider whether

Plaintiffs could have stated a claim for fraudulent misrepresentation based on the allegations included in the Master Complaint.

Notably, Plaintiffs do not meaningfully dispute that they have failed to even attempt to identify the bases for their fraudulent misrepresentation claim under Count VI. Instead, they claim the “specific allegations supporting each Plaintiff’s fraud claims will inevitably vary based on the information about the GLP-1 RAs that reached each Plaintiff,” and that is why each Plaintiff “will have an opportunity in the Short Form Complaint to set out those individual facts.” (Doc. No. 364 at 35; see also Apr. 21, 2025 Hr’g Tr. at 90:14–22 (Plaintiffs’ counsel stating that if “somebody has a genuine fraud claim,” then they will provide additional facts in the short form complaint because “that will require some specificity as to that plaintiffs’ factual circumstances”); *id.* at 93:5–14 (explaining that Count VI was left as a placeholder claim because Plaintiffs’ counsel “didn’t feel like all of the elements of the fraud claim were something we wanted to plead on a master basis,” and that individual Plaintiffs “could do that individually if they felt like they had . . . been deceived by some specific misrepresentation”).) But the proposed short form complaints already include a place for individual Plaintiffs to include any additional counts for which they can sufficiently plead supporting facts. (*See* Doc. No. 387-2 at 7.) Thus, in addition to providing no notice to Defendants as to the bases for the fraudulent misrepresentation claim, including a “placeholder” count for fraudulent misrepresentation in the Master Complaint seems both superfluous and likely to cause confusion.

Accordingly, the motion to dismiss Count VI is granted. The Court declines to allow Count VI to proceed as a “placeholder” count on a master basis. However, Plaintiffs’ lead counsel may file an amended master complaint to the extent they wish to assert fraudulent

misrepresentation claims that are coextensive with their other misrepresentation claims or otherwise believe they can plead fraudulent misrepresentation with sufficient specificity.

Alternatively, if Plaintiffs' lead counsel choose not to plead fraudulent misrepresentation on a master basis, any Plaintiff who believes they can state a claim for fraudulent misrepresentation may include that claim and their supporting allegations in their short form complaint.

*c. Remaining Counts for Misrepresentation (Counts VIII–X)*

That leaves Plaintiffs' remaining misrepresentation claims. Plaintiffs bring three additional common law counts for affirmative misrepresentation: negligent misrepresentation/marketing (Count VII), strict product liability misrepresentation/marketing (Count IX), and innocent misrepresentation/marketing (Count X). (*See* Doc. No. 294 at p. 205 & ¶¶ 765–803.) The specific elements for each count will vary depending on the applicable state's laws. *See, e.g., Merchants Com. Bank v. Oceanside Vill., Inc.*, CASE NO. ST-2011-CV-653, 2015 WL 9855658, at \*10–11 (V.I. Super. Dec. 18, 2015) (explaining that “other jurisdictions define negligent misrepresentation by considering the defendant’s misrepresentation; the plaintiff’s reliance on that representation; . . . the damages suffered by the plaintiff[;] the context in which the representation was made[;] and the degree of care exercised in making the representation” and then outlining the different interpretations of those elements across jurisdictions); Restatement (Second) of Torts § 552 (defining liability for information negligently supplied for the guidance of others (i.e., negligent misrepresentation)); *id.* § 552C (defining liability for misrepresentations made in a sale, rental, or exchange transaction (i.e., innocent misrepresentation)); *Kailin v. Armstrong*, 643 N.W.2d 132, 148 n.23 (Wis. Ct. App. 2002) (outlining the elements of strict liability misrepresentation). However, the Court need not delve into variations in state law, or even variations in the elements of each category of

misrepresentation (i.e., negligent, strict liability, innocent), in this Memorandum because Defendants’ motion focuses on one element common to all: whether Plaintiffs have identified an affirmative misrepresentation with the specificity required by Rule 9(b). (*See* Doc. No. 329-1 at 25–26 (“Plaintiffs’ allegations “are the quintessentially vague and overly generalized allegations that courts reject as failing to meet Rule 9(b).”); Apr. 21, 2025 Hr’g Tr. at 18:23–22:8 (“I recognize there are a lot of paragraphs here, but one of the things that’s notably absent in this Complaint is any type of specificity about where misrepresentations occurred and what they are.”); *id.* at 108:24–109:1 (“They have to do more to be specific about where there was any type of falsity and what that falsity was.”)).<sup>17</sup>

Defendants describe Plaintiffs’ allegations as “boilerplate” assertions, which “do not describe the ‘who, what, when, where, and how’” or identify the specific communications and

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<sup>17</sup> Plaintiffs argue that Counts VIII through X should be analyzed under Rule 8(a)’s more lenient standard. The Court disagrees. Although Plaintiffs’ fraudulent omission (Count V) and fraudulent misrepresentation (Count VI) claims are clearly governed by Rule 9(b) because fraud is a necessary element of both claims, it is a little trickier to discern whether Plaintiffs’ remaining misrepresentation claims (Counts VIII through X) should be considered under Rule 9(b) or Rule 8 because fraud is not a necessary element of those claims and at times, Plaintiffs’ assertions mix the two standards. For example, in support of their negligent misrepresentation claim, Plaintiffs allege that “Defendants *negligently* provided Plaintiffs, Plaintiffs’ prescribing physicians, the general medical community, and the public with false, *fraudulent*, and/or incorrect information or omitted or failed to disclose material information concerning GLP-1 RA Products.” (Doc. No. 294 at ¶ 766 (emphasis added); *accord id.* at ¶¶ 767, 769.) Despite these somewhat confusing assertions, the Court nevertheless finds that all the misrepresentation counts are appropriately considered under Rule 9(b)’s more stringent standard because Plaintiffs’ misrepresentation claims, at their core, are based on allegations of knowing and intentional misconduct. (*See, e.g., id.* at ¶ 588 (“Defendants’ Marketing of GLP-1 RAs Was *Intentionally* Deceptive and Misleading and Lacked Fair Balance.” (emphasis added)); *id.* at ¶ 769 (“Defendants’ conduct had the capacity to deceive and/or [their] *purpose* in making these misrepresentations was *to deceive and defraud* the public and the medical community, including Plaintiffs and Plaintiffs’ health care providers; to falsely assure them of the quality of GLP-1 RA Products and induce the public and medical community, including Plaintiffs and Plaintiffs’ prescribing physicians to request, recommend, purchase, and prescribe GLP-1 RA Products.” (emphases added)); *id.* at ¶ 774 (“Defendants made the misrepresentations alleged herein *with the intent* to induce consumers, like Plaintiffs, to take their diabetes treatment product.” (emphasis added)); *see In re Westinghouse Sec. Litig.*, 90 F.3d at 717 n.21 (describing allegations in a previous case as “sounding in fraud” because the plaintiffs there alleged “intentional, knowing, and reckless conduct”).

“documents in which either Novo or Lilly made any misstatements.” (Doc. No. 294 at 26–27.) Plaintiffs respond that they have sufficiently alleged that Defendants misrepresented both the weight loss benefits and the safety of their medications in a variety of communications to consumers and to physicians. The Court addresses each category of misrepresentations in turn.

i. Weight Loss Benefits

First, Plaintiffs claim that Defendants misrepresented the “long-term effects of GLP-1 RA Products.” (*Id.* at ¶ 767; *see also, e.g., id.* at ¶ 791 (alleging Defendants misrepresented the efficacy of their medications).) Plaintiffs allege that Defendants, and scientists and pharmaceutical representatives connected with Defendants, touted the weight loss benefits of the GLP-1 RAs to consumers via specific commercials, social media campaigns, and website assertions, and to physicians via scientific articles and presentations, even though many of the medications were not adequately tested for weight loss, approved for that indication, or as effective as Defendants’ communications suggested. (*See* Doc. No. 294 at ¶¶ 317–415, 590–612, 768, 773; *see also* Apr. 21, 2025 Hr’g Tr. at 85:2–86:6 (discussing misrepresentations related to weight loss).) The Court finds Plaintiffs have identified Defendants’ weight loss misrepresentations to consumers with the specificity required by Rule 9(b). They have not, however, sufficiently identified any misrepresentations in communications made to physicians to allow this portion of their claims to survive.

Beginning with the communications to consumers, the Master Complaint identifies numerous specific advertisements and statements by Defendants to consumers about the weight loss benefits of GLP-1 RAs. (Doc. No. 294 at ¶ 372 (describing Ozempic commercial, which stated, “you may lose weight” and “adults lost on average up to 12 pounds”), *id.* at ¶ 380 (describing Trulicity commercials in which the actor stated, “I may even lose a little weight,”

and which noted that taking Trulicity can help individuals “lose up to 10lbs”); *id.* at ¶¶ 383–84 (describing Simone Biles posting a video on Instagram, which stated, “people taking Mounjaro lost up to 25 pounds,” and a February 12, 2023 Super Bowl ad that stated the same); *id.* at ¶¶ 405–08 (describing Ozempic advertisements that touted potential weight loss effects before semaglutide (marketed as Wegovy) received FDA authorization for that indication); *id.* at ¶ 409 (describing statements on Novo’s Ozempic website, including assertions related to Ozempic’s “superior weight reduction”); *id.* at ¶¶ 414–15 (describing similar statements on Lilly’s website for Mounjaro and in commercials promoting Mounjaro).)

According to Plaintiffs, Defendants knowingly and intentionally misrepresented the efficacy of the drugs in these statements, suggesting all the GLP-1 RAs lead to substantial, healthy, long-term weight loss, when in truth, many patients fail to lose weight because they stop taking their GLP-1 RAs within a few weeks of starting them and/or gain the weight back when they stop taking them. (*Id.* at ¶¶ 99–102 (describing data and studies published by Defendants showing “weight loss for semaglutide users is likely to plateau” and that “patients who discontinued use of semaglutide ‘gradually regained weight’”); *id.* at ¶ 590 (describing data and studies that “suggest[ ] that both Novo and Lilly overstated the weight loss benefits of their drugs in advertisements”); *id.* at ¶¶ 592–96 (discussing articles and Defendants’ publications and statements which suggest “most individuals will regain all the weight back” after they stop taking their GLP-1 RA); *id.* at ¶¶ 609–12 (citing studies which show “[a]pproximately 58% of patients stop taking a GLP-1 RA within 12 weeks, and 30 percent stop in the first 4 weeks” and noting that “[n]either Novo or Lilly warns or highlights that most people are unable to tolerate the drug and stay on it long enough for it to make a meaningful difference”).)

The Court finds these allegations place Defendants on notice of the weight loss misrepresentations to consumers which may be alleged by each Plaintiff.<sup>18</sup> *See In re Allergan*, 537 F. Supp. 3d at 735 (finding the master complaint satisfied heightened pleading standard under Rule 9 because it provided “the essential factual background of [the pharmaceutical manufacturer’s] alleged misrepresentations of its implants that lack any reference to the BIA-ALCL risk,” including, for example, a “publicly available online video,” which referenced the “greatly improved safety” of breast augmentation and described the manufacturers “textured and smooth implants” but failed to “make any distinction between the two types of implants as to the significantly increased risk of contracting BIA-ALCL associated with the textured type,” thus implying that the manufacturer’s “textured implants . . . enjoy a greatly improved safety feature comparable to smooth implants”); *In re Valsartan*, MDL No. 19-2875 (RBK/KW), 2021 WL 12142025, at \*11 (D.N.J. Oct. 7, 2021) (finding the plaintiffs’ master complaint adequately stated fraud-based claims including fraudulent and negligent misrepresentation, fraud by omission, fraudulent concealment, and violation of consumer protection statutes by alleging the “who, what, where, and when”: “[t]he ‘who’ is each Defendant. The ‘what’ is the representations that the [drugs] were manufactured in compliance with [accepted practice] and were therapeutically equivalent to their reference listed drugs. The ‘where’ and ‘when’ are the materials that accompanied the sales of the [drugs]”); *cf. Suttman-Villars v. Argon Med.*

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<sup>18</sup> Defendants argue that these statements cannot form the basis of a negligent misrepresentation claim because they are not “quantifiable and measurable.” (Doc. No. 329-1 at 30–31.) But the statements identified by Plaintiffs (and quoted in the parentheses) are quantifiable; the parties are certainly capable of determining the truth of Lilly’s assertion that “people taking Mounjaro lost up to 25 pounds” and Novo’s assertion that adults “lost on average up to 12 pounds.” In other words, these are “actionable statements of fact” that are “quantifiable and measurable against a specific standard,” not mere “puffery.” *Doe A.F. v. Lyft, Inc.*, CIVIL ACTION NO. 23-3990-KSM, 2024 WL 3497886, at \*7 (E.D. Pa. July 19, 2024).



*Devices, Inc.*, 553 F. Supp. 3d 946, 962–63 (D.N.M. 2021) (finding the plaintiff’s allegations satisfied Rule 9(b) where they showed “Defendants made material representations about the [medical device’s] efficacy and safety to Plaintiff and her healthcare providers”).

Plaintiffs argue that they have similarly alleged sufficient facts to show Defendants made misrepresentations *to physicians* about the weight loss benefits of the drugs. But they have only vaguely referenced communications to the medical community in scientific presentations and in articles. For example, Plaintiffs broadly allege that Defendants offer “robust continuing medical education” programs that “encourage[ ] drugs for weight loss” (Doc. No. 294 at ¶¶ 345–49) and that Defendants “present at industry and academic conferences on the topic of obesity” where they “advocate[ ] for ‘clinically-based care’ for obesity, which primarily means use of GLP-1 RAs” (*id.* at ¶¶ 350–51). Plaintiffs have not, however, identified when these representations were made, described the statements, or explained why they are misleading. Similarly, Plaintiffs allege that Defendants are “involved directly or indirectly in significant amounts of literature intended to influence doctors’ perceptions of obesity, treatment for obesity and the safety and efficacy of GLP-1 RAs.” (*Id.* at ¶ 352.) Although they identify multiple specific articles that were allegedly funded by Defendants, they have not explained why these third-party statements should be considered misrepresentations *by Defendants* or alleged that articles promoting pharmaceutical treatment of obesity are in fact, false or misleading. (*See id.* at ¶¶ 353–56.)

Accordingly, the Court finds that Plaintiffs have sufficiently alleged that Defendants misrepresented the weight loss benefits of their GLP-1 RAs in the identified communications to

consumers.<sup>19</sup> They have not, however, sufficiently identified misrepresentations in communications made to physicians. Plaintiffs’ lead counsel will be given an opportunity to amend the Master Complaint to include such allegations if they can do so in good faith.

ii. Safety of the Medications

Second, Plaintiffs claim that Defendants misrepresented that their GLP-1 RAs were safe in various communications to physicians and the public, despite knowing the drugs could cause the Alleged Injuries. (*See* Doc. No. 294 at ¶¶ 768–73 (alleging Defendants misrepresented the safety risks associated with their GLP-1 RA products in “advertising campaigns, labeling materials, print advertisements, commercial media, and marketing”); *id.* at ¶ 791 (“Defendants made material misrepresentations to Plaintiffs, Plaintiffs’ prescribing physicians, the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of their GLP-1 RA Products.”); *id.* at ¶ 792 (alleging Defendants misrepresented the “causal association” between their medications and the Alleged Injuries).) To the extent Plaintiffs are relying on communications in the drugs’ labels, the Court finds Plaintiffs have identified the misstatements with the necessary specificity. As for the remaining safety allegations, however, the Court agrees that Plaintiffs have failed to state a claim.

Beginning with Defendants’ statements in the GLP-1 RAs labels, this portion of Plaintiffs’ misrepresentation claims appears to be the flip side of Plaintiffs’ fraudulent omission claims. Just as the Plaintiffs allege that Defendants omitted the risks that each medication would cause one or more of the Alleged Injuries from the medications’ labels, they also argue

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<sup>19</sup> One caveat to this ruling is Plaintiffs’ allegations of justifiable reliance on these misrepresentations. To the extent justifiable reliance is an element of any Plaintiff’s misrepresentation claim(s), all parties agree that they must allege facts tending to show reliance in their short form complaint.

that the warnings which were included misrepresented the extent to which each GLP-1 RA could cause adverse gastrointestinal side effects. (*See id.* at ¶ 468 (“At all relevant times, [t]he ‘Adverse Reactions’ sections of Novo Nordisk’s labels for Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide), Victoza (liraglutide), and Saxenda (liraglutide) all inadequately referenced ‘common adverse reactions’ including ‘nausea, vomiting, diarrhea, stomach (abdominal) pain, and constipation.’ These vague references provided no notice of the magnitude of these conditions effectively downplaying the risks . . . [and] inaccurately suggest[ing] these conditions will decrease over time and downplay[ing] the intensity and range of conditions that patients face, including the potential for hospitalization, long-term damage to vital organs and the need for surgical intervention, disability and death.”); *id.* at ¶¶ 469–75 (similar allegations for Lilly’s medications, Trulicity (dulaglutide), Mounjaro (tirzepatide), and Zepbound (tirzepatide)).) These allegations, which identify the specific sections and statements within each label that contain the allegedly misleading communications, and explain why those statements are misleading, satisfy Rule 9(b).

As to claims for communications made outside the medications’ labels, however, the Court finds that Plaintiffs have not identified the communications with any specificity, let alone explained how general statements that a prescription medication is “safe” are misleading. Instead, Plaintiffs speak in general terms of “additional misrepresentations” that the drugs are “safe.” (*See id.* at ¶ 772 (“Defendants made additional misrepresentations beyond the product labeling by representing GLP-1 RA Products as safe and effective for diabetes with only minimal risks.”).) Because Plaintiffs do not identify these misrepresentations with enough specificity to know when the communications were made, by whom, or what was said, they do not satisfy Rule 9(b) and are dismissed. *See King*, 2022 WL 2341633, at \*6 (dismissing

misrepresentation claims under Rule 9(b) where the plaintiff alleged that defendants falsely represented that their pharmaceutical product was “safe, effective, [and] reliable” but failed to plead “the ‘contents’ of the misrepresentations,” “the place or manner of the misrepresentations,” and the “time when Defendants allegedly made misleading statements”); *Bentley v. Merck & Co, Inc.*, CIVIL ACTION NO. 17-1122, et al., 2017 WL 2349708, at \*2 (E.D. Pa. May 30, 2017) (“Plaintiffs baldly assert that defendants falsely represented to unnamed individuals, on unspecified dates, that Zostavax was safe and effective. They have failed to allege the date, place, time, and source of the misrepresentations with respect to any of the plaintiffs. They never identify the specific misrepresentation in issue, or when or where they occurred. . . . Plaintiffs have failed to allege fraud with sufficient particularity to put defendants on notice of the precise misconduct with which it is charged.”).

In sum, the Court finds that Plaintiffs have sufficiently alleged Defendants misrepresented the risks associated with GLP-1 RAs in the medications’ labels.<sup>20</sup> They have not, however, sufficiently alleged similar misrepresentations in other communications to physicians. Plaintiffs’ lead counsel will be given an opportunity to amend the Master Complaint to include such allegations if they can do so in good faith.

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In sum, Defendants’ motion to dismiss is denied in part and granted in part as to Counts VIII through X. The motion is denied to the extent Counts VIII through X are based on misrepresentations to consumers about the medications’ weight loss benefits and

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<sup>20</sup> Again, one caveat to this ruling is Plaintiffs’ allegations of justifiable reliance on these misrepresentations. *See supra* n.19. To the extent reliance is an element of any Plaintiff’s misrepresentation claim(s), all parties agree that they must allege facts tending to show reliance in their short form complaint.

misrepresentations in the drugs’ labels about the risks associated with taking the medications. The motion is granted to the extent Counts VIII through X are based on unidentified communications to physicians and the medical community about the drugs’ weight loss benefits, or the medications’ safety (to the extent the communications were made outside of the labels).

#### 4. Design Defect Claims (Counts XI and XII)

Next, Defendants challenge Plaintiffs’ design defect claims (Count XI and XII) to the extent they bring “pure” design defect claims (i.e., claims based on the drugs’ formulation and dosage) as opposed to warning-based design defect claims. (Apr. 21, 2025 Hr’g Tr. at 54:6–56:12; *see also, e.g.*, Doc. No. 294 at ¶ 808 (“Defendants GLP-1 RA Products were defective in design or formulation . . . .”); *id.* at ¶ 820 (same).)<sup>21</sup> Defendants argue that the pure design defect claims asserted in both counts are preempted by federal law. (Doc. No. 329-1 at 35–40.) The Court agrees.<sup>22</sup>

The Supremacy Clause of the United States Constitution “establishes that federal law ‘shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.’” *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (quoting U.S. Const. Art. VI, cl. 2). “Accordingly, it has long been settled that state laws that conflict with federal law are without effect.” *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013) (quotation marks omitted). “Even in the absence of an express pre-emption provision,

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<sup>21</sup> Generally, a design defect claim alleges that a properly manufactured product is “unreasonably dangerous because its attributes can cause unexpected injuries.” *In re Valsartan*, 2021 WL 307486, at \*18. Some states, however, recognize that failure to provide adequate warnings can result in a defective design. Here, Defendants focus on the former claim, not the latter, arguing that Plaintiffs’ pure design defect claims are preempted by federal law

<sup>22</sup> Defendants also argue that Plaintiffs have failed to plead a plausible claim for design defect; however, because the Court finds the pure design defect claims preempted, we need not determine whether Plaintiffs’ allegations are sufficient.

the Court has found state law to be impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements”—i.e., “impossibility pre-emption.” *Id.* at 480 (quotation marks omitted); *see also Mensing*, 564 U.S. at 617–18 (finding state law failure to warn claims preempted because state law placed a duty on generic drug manufacturers to adequately and safely label their products, but federal regulations prevented the drug manufacturers from independently changing their drugs’ safety labels).

The Supreme Court has analyzed preemption in the prescription drug context numerous times. *See, e.g., Bartlett*, 570 U.S. at 490 (holding that state law design defect claims which “place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling”); *Mensing*, 564 U.S. at 617–18 (finding state law failure to warn claims preempted because state law placed a duty on generic drug manufacturers to adequately and safely label their products but federal regulations required generic labels to be the same as brand name labels and thus, prevented the drug manufacturers from independently changing their drugs’ safety labels); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that “the plaintiffs’ state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law”).

Defendants, citing *Bartlett*, argue that impossibility preemption bars Plaintiffs’ design defect claims to the extent they allege that GLP-1 RAs were “defective in design or formulation,”<sup>23</sup> because the FDA regulations that prohibited the generic manufacturers in

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<sup>23</sup> Again, Defendants’ argument is a narrow one, in that it “focuses only on Plaintiffs’ design-defect claims challenging the medicines’ formulation,” and does not argue for dismissal of Plaintiffs’ failure to warn claims, which will be addressed in later motion practice. (Doc. No. 329-1 at 38 n.8; *see also id.* at 39 (“Plaintiffs cannot avoid preemption of their pure design-defect claims (*i.e.*, claims that go

*Bartlett* from unilaterally changing the design, formulation, or chemical composition of their drugs, likewise prohibit brand name manufacturers from unilaterally changing the design of their drugs. (Doc. No. 329-1 at 38.) Although the Third Circuit has not addressed this precise issue,<sup>24</sup> at least three federal appellate courts have found pure design defect claims against brand name manufacturers preempted under *Bartlett* where the applicable state law would have required the manufacturer to alter its drug in a way that it could not without first receiving FDA approval. *See Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 10 (1st Cir. 2018) (“Controlling case law is clear—and plaintiffs here concede—that if the change they contend state law requires qualifies as ‘major,’ then federal law preempts plaintiffs’ cause of action because defendants cannot lawfully make such a change without prior FDA approval.”); *accord Ignacinos v. Boehringer Ingelheim Pharms., Inc.*, 8 F.4th 98, 101 (2d Cir. 2021); *see also id.* at 102–05 (holding that plaintiffs’ state law claims against a brand name manufacturer were preempted because they would have “require[d] either an increase in the amount of [medication] per cartridge or a change in the design of the inhaler to release more doses from the same amount of medication,” both of which were major changes requiring FDA pre-approval); *Gustavsen*, 903 F.3d at 4 (holding that “state law claims challenging [brand name and generic drug] manufacturers’ refusal to” change “the medication’s bottle so as to alter the amount of medication dispensed into the eye” were preempted because such a change required pre-approval by the FDA); *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281, 298–99 (6th Cir. 2015) (“We think it clear that changing the dosage level of the active

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to the composition of the product itself.”); Doc. No. 392 at 23 (“Plaintiffs’ claims about formulation, design, and dosing are . . . preempted.”).)

<sup>24</sup> Although the Third Circuit has addressed preemption of failure to warn claims brought against brand name drug manufacturers, *see generally In re Fosamax*, 118 F.4th 322 (3d Cir. 2024), it has not addressed preemption of pure design defect claims brought against brand name manufacturers.

ingredient in ORTHO EVRA constitutes a ‘major change,’ such that prior FDA approval is necessary. Therefore, to the extent Yates argues that defendants should have altered the formulation of ORTHO EVRA after the FDA approved the patch, we find this claim clearly preempted.” (internal citation omitted)).

We find these cases persuasive and thus, part ways with those cases that can be read as holding *Bartlett*’s preemption ruling is always inapplicable to brand name drugs. See *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.* (“*In re Tylenol*”), MDL NO. 2436, 2:13-md-02436, 2015 WL 7075949, at \*22 (E.D. Pa. Nov. 13, 2015). It is true that the *Mensing* Court distinguished the duties imposed on generic manufacturers from those imposed on brand name manufacturers. See 564 U.S. at 613 (recognizing that “brand-name and generic drug manufacturers have different federal drug labeling duties,” finding that, contrary to the brand name manufacturer regulations, federal law did not permit generic drug manufacturers to “use[ ] the CBE process or Dear Doctor letters to strengthen their warning labels,” and holding that impossibility preemption foreclosed state law failure to warn claims because it “was not lawful under federal law for the [generic] Manufacturers to do what state law required of them”); see also *id.* at 626 (“[D]ifferent federal statutes and regulations may, as here, lead to different pre-emption results.”). But it does not follow that the Supreme Court’s preemption rulings involving generic manufacturers *never* apply in cases against brand name manufacturers.

As relevant here, although brand name and generic drug manufacturers have different labeling duties, see *Mensing*, 564 U.S. at 613, they are subject to the same regulations when it comes to a post-approval change to a drug’s formula or dosage, see *Bartlett*, 570 U.S. at 477 (“Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the ‘qualitative or quantitative formulation of the drug



product, including active ingredients, or in the specifications provided in the approved application.” (quoting 21 C.F.R. § 314.70(b)(2)(i)). Section 314.70(b)(2)(i) categorizes any change to a drug’s formula or dosage as a “major change” requiring FDA approval. *See* 21 C.F.R. § 314.70(b)(2)(i). In other words, a drug manufacturer, whether brand name or generic, cannot independently implement such a change. In *Bartlett*, the Court recognized that a generic drug manufacturer does “not have the option of changing [the drug’s] design.” *Bartlett*, 570 U.S. at 482; *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)* (“*In re Fosamax*”), 751 F.3d 150, 164 (3d Cir. 2014) (“[T]he *Bartlett* decision clearly holds that . . . a redesign [of a generic drug] is impossible under federal law for a generic drug manufacturer.”); *cf. Mensing*, 564 U.S. at 623–24 (“[W]hen a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.”). Because the same regulation governs brand name drugs, this finding of impossibility would seem to apply with equal force to a pure design defect claim brought against a brand name manufacturer. The Court finds as much here.

Because brand name manufacturers, like generic drug manufacturers, cannot alter the makeup of a drug without pre-approval from the FDA, Plaintiffs’ state law design defect claims are preempted to the extent that they would require Defendants to alter the formula or dosage of their GLP-1 RAs. *See Ignaciuinos*, 8 F.4th at 102–05; *Gustavsen*, 903 F.3d at 4; *Yates*, 808 F.3d at 298–99; *cf. Bartlett*, 570 U.S. at 490 (“[W]e hold that state-law design-defect claims like New Hampshire’s that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from *unilaterally* altering drug composition or labeling.” (emphasis added)); *Mensing*, 564 U.S.

at 618 (“If the Manufacturers had *independently* changed their labels to satisfy their state-law duty, they would have violated federal law. . . . Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.”).

Plaintiffs “agree with the general proposition . . . that state-law design-defect claims that would require Defendants to reformulate their drugs to comply with state law will be preempted because the FDA will not normally allow the manufacturer to alter the formulation of its drug without prior agency approval.” (Doc. No. 364 at 48.) But, they argue, the Court should not find all such claims per se preempted because there are circumstances that could “give rise to non-preempted design-defect claims” in individual cases. (*Id.* at 49.) They propose three exceptions—one for parallel misbranding claims, one for marketing-based claims, and one for claims based on the existence of a safer alternative formulation. The Court addresses each in turn.

*a. The “Parallel Misbranding” Exception*

First, Plaintiffs argue that some “state design-defect claims . . . parallel the federal misbranding statute,” rendering it possible to comply with both state and federal law. (*Id.* at 49.) Under that statute, “[a] drug or device shall be deemed to be misbranded” if, among other things, “it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.” 21 U.S.C. § 352(j). Manufacturers are prohibited from placing misbranded drugs in interstate commerce. *Id.* § 331(a), (g); *see also Bartlett*, 570 U.S. at 487 n.4 (“The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is ‘dangerous to health’ even if ‘used in the dosage or manner, or with the frequency or duration prescribed,

recommended, or suggested in the labeling thereof.” (quoting 21 U.S.C. § 352(j))). In what courts refer to simply as “Footnote 4,” the *Bartlett* Court declined to consider whether its preemption decision applied to “state design-defect claims that parallel the federal misbranding statute” because “the misbranding provision” did not apply in that case. *Bartlett*, 570 U.S. at 487 n.4. Though “the parties and the Government [agreed] that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA,” the jury had not been “asked to find whether new evidence concerning [the drug at issue] that had not been available to the FDA rendered [it] so dangerous as to be misbranded under the federal misbranding statute.” *Id.*

Here, Plaintiffs argue that they, unlike the plaintiff in *Bartlett*, have adequately alleged that Defendants had information to show that the GLP-1 RAs were dangerous to health even when taken in approved doses and that this information was not considered by FDA, such that the drugs were misbranded and federal and state law would be coextensive in finding the drugs’ continued sale unlawful. (See Doc. No. 364 at 49 n.14 (citing Doc. No. 294 at ¶¶ 438–45, 454–587).) Defendants counter that nothing in Footnote 4 overrules the Supreme Court’s holding in *Bartlett* that pure design defect claims are preempted or the Court’s prior rulings in *Mensing* and *Buckman*. (Doc. No. 392 at 23–24.)

Although the Third Circuit has not considered the effect of Footnote 4, the Sixth Circuit has. See *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.* (“*In re Darvocet*”), 756 F.3d 917, 928 (6th Cir. 2014). *In re Darvocet* was an MDL action consolidating 68 claims “against both generic and brand-name manufacturers for personal injuries related to the use of the drug propoxyphene.” 756 F.3d at 922. The “central claim” in that case was that generic drug manufacturers of propoxyphene “wrongfully marketed an unreasonably dangerous

product” and continued to sell propoxyphene even when they “knew or should have known that its risks outweighed its utility.” *Id.* at 927. The plaintiffs asserted this conduct was “actionable under a variety of legal theories, including strict liability design defect [and] negligent design.” *Id.* The district court dismissed those claims as preempted before the Supreme Court issued its ruling in *Bartlett*, and on appeal, the plaintiffs argued that they should be reinstated because they fell into the “parallel misbranding” exception outlined in Footnote 4. *Id.*

On appeal, the Sixth Circuit considered the “genesis” of Footnote 4, explaining that the “parallel misbranding” exception was argued in the FDA’s amicus brief in *Bartlett*:

In *Bartlett*, the FDA argued in an amicus brief that *Mensing*’s preemption analysis applied only to claims that turn on the adequacy of the drug labeling. The FDA distinguished those claims from “pure” design defect claims, which it argued are preempted unless they “parallel the FDCA’s drug misbranding prohibition.” The FDA continued, “A manufacturer has a federal duty not to market a drug if, *inter alia*, it is ‘dangerous to health’ when used as provided in the labeling. A state-law duty not to market the drug in the same circumstances would not conflict with federal law if it appropriately accounted for the FDA’s role under the FDCA.”

*Id.* at 929 (quoting FDA Br., *Bartlett*, 2013 WL 314460, at \*23) (alterations adopted). In Footnote 4, the Supreme Court responded to this argument by “remarking that its holding ‘does not address state design defect claims that parallel the federal misbranding statute.’” *Id.* (quoting *Bartlett*, 570 U.S. at 487 n.4). The Sixth Circuit found it was “not clear whether this language implies that an exception for ‘parallel misbranding’ claims actually exists.” *Id.* Nevertheless, the court found it did not need to decide this “possibly thorny issue,” because the plaintiffs had failed to plead such a claim. *Id.* at 929–30. Specifically, the plaintiffs had not identified the specific state claims “that parallel . . . a federal misbranding claim under 21 U.S.C. § 352(j),” nor had they identified “‘new and scientifically significant information’ that the Generic Manufacturers possessed that was not before the FDA.” *Id.* at 930.

In the years since *In re Darvocet*, no appellate court has decided the “thorny issue” of whether *Bartlett* creates a “parallel misbranding” exception to preemption. For two reasons, this Court also declines to rule on the issue here. First, the parties’ briefing on the issue is slim. Plaintiffs’ argument in favor of this exception consists of four sentences quoting *Bartlett*. (*See* Doc. No. 364 at 49 & n.14.) They do not discuss the confused state of the case law, the scope of Footnote 4, or how the allegations in the Master Complaint plausibly suggest that the exception applies (assuming it exists at all). (*See id.*) Nor did they discuss the issue during oral argument on the motion to dismiss. (*See generally* Apr. 21, 2025 Hr’g Tr.) Meanwhile, Defendants’ arguments against the exception—although providing a more thorough discussion of Footnote 4, its origins, and the subsequent case law—attempt to package the nuances of multiple Supreme Court preemption opinions into just a few paragraphs of a reply brief. (*See* Doc. No. 392 at 23–24 (discussing *Bartlett*, *Mensing*, and *Buckman*).)<sup>25</sup> Second, even if Plaintiffs had provided sufficient briefing on this issue, they, like the plaintiffs in *In re Darvocet*, have not identified “claims from states at issue that parallel . . . a federal misbranding claim under 21 U.S.C. § 352(j),” nor have they alleged with specificity the “‘new and scientifically significant information’ that [Defendants] possessed that was not before the FDA.” 756 F.3d at 930. Instead, they broadly refer to 140 paragraphs of the Master Complaint (*see* Doc. No. 364 at 49

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<sup>25</sup> Among other issues, the parties have not addressed whether the “parallel misbranding” exception applies only to warning-based design defect claims, design defect claims premised on marketing, pure design defect claims, or some combination of the three. *See Bartlett*, 570 U.S. at 487 & n.4 (attaching Footnote 4 to its holding that “New Hampshire’s *warning-based* design-defect cause of action is pre-empted,” and in that footnote, including a citation to *Bates v. Dow Agrosciences LLC*, which the Court characterized as finding “state-law pesticide labeling requirement was not pre-empted under express pre-emption provision, provided it was ‘equivalent to, and fully consistent with, federal misbranding provisions’” (emphasis added and alterations adopted)); *In re Darvocet*, 756 F.3d at 930 (discussing the exception in the context of the plaintiffs’ “wrongful marketing claims”); *In re Yasmin*, 2015 WL 7272766, at \*4 (“Assuming *Bartlett* allows an exception for parallel misbranding claims, the exception only applies to ‘pure’ design defect claims *i.e.* design defect claims that do *not* turn on the adequacy of drug labeling.”).

n.14), which vaguely allege that “Defendants’ research into their products put them in a position to be [sic] become aware, in the post-approval context, of the risks and danger of the use of GLP-1 RAs, including the risks of of [sic] developing” the Alleged Injuries (Doc. No. 294 at ¶ 439; *see also id.* at ¶¶ 444 (vaguely alleging that “Defendants intentionally withheld from or misrepresented to the FDA post-approval information concerning their GLP-1 RAs”)).

In short, Plaintiffs have not provided legal or factual support for the Court to apply a parallel misbranding exception in this case. Accordingly, we decline to read a parallel misbranding exception into the preemption of their pure design defect claims.

*b. Marketing-Based Claims*

Plaintiffs also argue that the Court should not find their pure design defect claims per se preempted because some state design defect claims apply when a drug is promoted “for a use for which it has not been approved by the FDA.” (Doc. No. 364 at 49.) Again, Plaintiffs provide no discussion of this exception, providing only a single sentence and citation in support of their argument. Plaintiffs rely on *In re TRT*, a case in which the defendant drug manufacturer argued that the plaintiff’s “design defect claims [we]re preempted because they would [have] require[d] a redesign of [the drug]—an action [the manufacturer] cannot take unilaterally.” 430 F. Supp. 3d at 531 (quotation marks omitted) (citing *Bartlett*, 570 U.S. at 490). The Illinois District Court found the defendant’s preemption argument “unavailing because [the plaintiff] d[id] not allege that [the manufacturer] needed to change the design of [the drug],” but instead, argued that the manufacturer “needed to stop marketing [the drug]” for off-label use. *Id.* Here, Defendants argue that *In re TRT* is “irrelevant” because they seek preemption only of the design defect “claims that challenge the medicines’ approved design, formulation, or dosing.” (Doc.

No. 392 at 24–25.) The Court agrees with Defendants. Given the narrow scope of their request for dismissal of the pure design defect claims, *In re TRT* has no bearing here.

*c. Safer Alternative Exception*

Last, Plaintiffs argue that “a plaintiff may assert a viable, non-preempted design defect claim where they allege not only that a defendant’s product was unreasonably dangerous, but also that another drug or a different dosage that was already on the market would have been a safer and more effective alternative.” (Doc. No. 364 at 49.) Again, Plaintiffs provide no explanation and cite only one case in support of this position, *In re Tylenol*. (*Id.*) In that case, the court found the plaintiffs’ design defect claims against the defendant brand name manufacturers were not preempted because unlike the generic manufacturers in *Bartlett*, “brand-name manufacturers . . . can petition the FDA to change their drug’s dosing, strength, etc. if the design poses a risk to consumers.” 2015 WL 7075949, at \*21–22 (citing *Wyeth v. Levine*, 555 U.S. 555, 581 (2009)). This was “especially true in the context of acetaminophen,” the drug at issue, because at the time, it was approved pursuant to “a TFM [tentative final monograph] and not a final monograph.” *Id.* Because the defendants operated under a “TFM—a proposed rule—the defendants could have [unilaterally] changed the dosing instructions prior to 2011.” *Id.* Based on these findings, the district court (1) refused to apply *Bartlett* in the brand name prescription context, and (2) found the plaintiffs could bring claims for design defect to the extent they argued that the defendants should have changed the dosing instructions to a safer, alternative option.

The Court declines to follow *In re Tylenol* here. First, as noted above, we part ways with *In re Tylenol* to the extent it can be read as holding *Bartlett*’s preemption ruling is per se inapplicable to brand name drugs. See *In re Tylenol*, 2015 WL 7075949, at \*22. Second, we

agree with Defendants that unlike their GLP-1 RAs, which were approved through the New Drug Application (“NDA”) process, acetaminophen was subject to a TFM, and thus, the defendants in *In re Tylenol* were permitted to unilaterally change the dosing instructions as a matter of federal law. By contrast, federal law does not permit changes to the formula or dosing of products that, like Defendants’ GLP-1 RA medications, are regulated by FDA-approved NDAs. *See* 21 C.F.R. § 314.70(b)(2)(i) (categorizing any change to an approved NDA drug’s formula or dosage as a “major change” requiring FDA pre-approval); *Bartlett*, 570 U.S. at 477 (“Once a drug—whether generic *or brand-name*—is approved, the manufacturer is prohibited from making any major changes to the ‘qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.’” (emphasis added) (quoting 21 C.F.R. § 314.70(b)(2)(i))).

Because brand name manufacturers, like generic drug manufacturers, cannot alter the makeup of a drug without pre-approval from the FDA, Plaintiffs’ state law claims are preempted to the extent that they would require Defendants to alter the formula or dosage of their GLP-1 RAs to be the same as a “safer alternative.” *See Ignaciuinos*, 8 F.4th at 102–05; *Gustavsen*, 903 F.3d at 4; *Yates*, 808 F.3d at 298–99; *cf. Bartlett*, 570 U.S. at 490 (“[W]e hold that state-law design-defect claims like New Hampshire’s that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from *unilaterally* altering drug composition or labeling.” (emphasis added)); *Mensing*, 564 U.S. at 618 (“If the Manufacturers had *independently* changed their labels to satisfy their state-law duty, they would have violated federal law. . . . Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.”). Accordingly, the Court rejects



Plaintiffs’ argument that their pure design defect claims survive preemption to the extent they identify a safer alternative.<sup>26</sup>

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In sum, Plaintiffs’ pure design defect claims are preempted. Plaintiffs will, however, be given an opportunity to amend the Master Complaint to the extent they can in good faith claim that the parallel misbranding exception applies.<sup>27</sup>

#### 5. Negligence (Count XIII)

Fifth, Defendants argue that Plaintiffs’ general claim for negligence (Count XIII) should be dismissed as redundant and inadequate because it merely repackages Plaintiffs’ failure to warn and design defects claims. (Doc. No. 329-1 at 40; *see also id.* at 40–41 (arguing that Count XIII “combines elements of manufacturing defect, design defect, and failure to warn”).) Although it is true that product liability claims are typically considered as falling into three buckets of negligent acts—defective manufacture, inadequate direction or warnings, and defective design—Defendants have not cited any cases which require that claims be divided in this way. And at least one other district court has refused to dismiss a “general negligence claim” from a master complaint. *See In re Hair Relaxer*, 702 F. Supp. 3d at 701 (finding Plaintiffs’ master longform complaint “stated a general negligence claim” where they alleged

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<sup>26</sup> The Court also questions Plaintiffs’ ability to proceed on this theory (assuming it were not preempted) when they have not identified a safer alternative. Indeed, Plaintiffs state in conclusory fashion that “a different drug or dosage on the market would have been a safer and more effective alternative” (Doc. No. 364 at 49), but they do not cite any paragraphs in the Master Complaint that support that assertion.

<sup>27</sup> To the extent Plaintiffs decide to amend their Master Complaint, they should first take heed of Defendants’ arguments as to why even a parallel misbranding claim is preempted under *Buckman*. (*See* Doc. No. 392 at 23–24.) And any future briefing by Plaintiffs on this exception must discuss the precedent and the arguments with the detail befitting an undecided issue arising out of a complicated history of Supreme Court jurisprudence.

that Defendants breached their “duty to exercise reasonable care in the advertising and sale of their hair relaxer products, including a duty to warn of risks associated with the products”).

During oral argument Defendants seemed to concede that Plaintiffs are not per se foreclosed from pleading a general negligence claim, and they reframed their challenge as raising a “case management question.” (Apr. 21, 2025 Hr’g Tr. at 27:18.) Defendants argue that to render the master complaint process “meaningful” and ensure the Master Complaint itself is “comprehensible,” Plaintiffs should be required to plead any general negligence claim with greater specificity and with a clear explanation as to how the claims in this count differ (or overlap) with the other negligence-based claims being asserted. (*Id.* at 27:18–29:4 (arguing that the “question is, does the count create confusion or is the count clear as to what is being alleged?” and that “when you look at the numbered paragraphs A through M and paragraph 834 and you try to connect that . . . to what the allegations, the substantive allegations are in the complaint, we don’t know what is being alleged”).)

The Court agrees that for the sake of clarity and efficiency—recognizing that thousands of individual Plaintiffs will use the Master Complaint to complete their short form complaints—Plaintiffs must clarify the nature of their general negligence claims. As Defendants aptly note, Count XIII is currently the “kitchen sink of negligence claims.” (Apr. 21, 2025 Hr’g Tr. at 27:3–8.) It broadly asserts every conceivable form of negligence, claiming “Defendants committed one or more of the following negligent acts or omissions:”

- a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing their GLP-1 RA Products, without thorough and adequate pre- and post-market testing of the products;
- b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing their GLP-1 RA Products, and upon information and belief,

while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risks of serious harm associated with the use of their GLP-1 RA Products;

- c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not their GLP-1 RA Products were safe for their intended uses;
- d. Upon information and belief, failing to disclose and warn of the products' defects to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that their GLP-1 RA Products were indeed unreasonably unsafe and unfit for use by reason of the products' defects and risks of harm to their users;
- e. Failing to warn Plaintiffs, the medical and healthcare community, and consumers that their GLP-1 RA Products' risks of harm were unreasonable and that there were safer and effective alternative products available to Plaintiffs and other consumers;
- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use their GLP-1 RA Products;
- g. Advertising, marketing, and recommending the use of their GLP-1 RA Products, while concealing and failing to disclose or warn of the dangers Defendants knew or should have known to be connected with, and inherent in, the use of their GLP-1 RA Products;
- h. Representing that their GLP-1 RA Products were safe for weight management when in fact Defendants knew and/or should have known the products were not safe for that purpose;
- i. Continuing to manufacture and sell their GLP-1 RA Products with the knowledge that their GLP-1 RA Products, when used for weight management, were unreasonably unsafe and dangerous;
- j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of their GLP-1 RA Products so as to avoid the risks of serious harm associated with the use of their GLP-1 RA Products. Failing to design and manufacture their GLP-1 RA Products so as to ensure the drugs were at least as safe and effective as other similar products;

- k. Failing to ensure that their GLP-1 RA Products were accompanied by proper and accurate warnings about the increased risks of [the Alleged Injuries];
- l. Failing to ensure that their GLP-1 RA Products were accompanied by proper and accurate warnings about possible adverse side effects associated with the use of their GLP-1 RA Products and that use of their GLP-1 RA Products created a high risk of severe and debilitating injuries; and defects to the regulatory agencies, the medical community, and consumers that
- m. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of their GLP-1 RA Products.

(Doc. No. 294 at ¶ 834.) The claims asserted in these paragraphs often overlap with each other and with the other negligence-based claims in the Master Complaint, including the independent claims for failure to warn, negligent misrepresentation/marketing, design defect, and negligent undertaking. At the same time, Count XIII seems to raise separate issues, including negligence in testing, distribution, and “post-marketing surveillance.” (*Id.*)

Plaintiffs concede that Count XIII “lump[s] in multiple theories” of negligence, but nevertheless argue that a general negligence claim is necessary because “various states interpret” these types of claims “differently, [s]o preserving a negligence count that allows people to bring a negligent marketing claim when maybe it’s in a state where they don’t have the ability to bring a negligent undertaking claim, our argument is it’s a permissible function.” (Apr. 21, 2025 Hr’g Tr. at 95:14–96:16.) Plaintiffs also agree, however, that they are capable of “separat[ing] out” the various theories on which the general negligence claim is based. (*Id.* at 96:17–19.) The Court agrees that separation is the proper course.

Plaintiffs may assert a general negligence claim on a master basis, but if they choose to do so, counsel must more precisely identify the theories supporting such a claim. As currently written, Count XIII is too ambiguous for the Court to understand the extent to which this count

overlaps with theories asserted in other counts and/or raises new theories. Such confusion will only be compounded through the short form complaint process, when dozens of lawyers not associated with Plaintiffs' Co-Lead Counsel will have to interpret the Master Complaint in selecting the counts being asserted by their clients. Similarly, as the Court issues rulings on certain theories (e.g., design defect, failure to warn, etc.), it will be difficult, if not impossible, to know the extent to which those rulings affect the catch-all negligence claims in Count XIII.

Accordingly, Defendants' motion to dismiss is granted as to Count XIII with the understanding that Plaintiffs will be given a chance to file an amended master complaint that more precisely separates out the various theories supporting their general negligence claim and identifies the nature of the factual allegations supporting each theory.

#### 6. Negligent Undertaking (Count XIV)

Sixth, Defendants argue that Plaintiffs' negligent undertaking claim (Count XIV) fails because this type of claim is inapplicable in the prescription drug context, Plaintiffs have not pleaded the elements for such a claim, and Plaintiffs are erroneously trying to plead around the learned intermediary doctrine. (Doc. No. 329-1 at 41–43.)

The Second Restatement of Torts § 323 describes the tort of negligent undertaking:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking if

- (a) his failure to exercise such care increases the risk of such harm, or
- (b) the harm is suffered because of the other's reliance upon the undertaking.

Restatement (Second) of Torts § 323 (Negligent Performance for Undertaking to Render Services). The Master Complaint alleges that Defendants, by conducting an extensive direct-to-consumer marketing campaign, voluntarily assumed a responsibility to communicate safety information directly to consumers. (Doc. No. 294 at ¶¶ 276–433, 842–62; *see also* Doc. No. 364 at 53–54 (“Their direct-to-consumer campaigns created an independent, actionable duty to the consumers who viewed and relied upon the advertisements to their detriment.”).)<sup>28</sup>

Courts have allowed negligent undertaking claims to proceed in the product liability context when the plaintiff alleges that the defendant took steps to warn them about the dangers of its product but the warning was inadequate. *See Fox v. Amazon.com, Inc.*, 930 F.3d 415, 427 (6th Cir. 2019) (“Applying § 323 and § 324A to the facts of this case, Defendant chose to send the December 12, 2015 email to Plaintiff Megan Fox, and in doing so plainly sought to warn her of the dangers posed by the hoverboard. . . . Given that Defendant assumed a duty to act, there remains genuine issues of material fact regarding whether Defendant breached that duty and whether any breach caused Plaintiffs physical harm. For instance, there is a genuine issue of material fact regarding whether Defendants’ failure to include certain information in the December 12, 2015 email amounted to negligence.”); *cf. Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 264 (3d Cir. 2010) (“In order for Spotts, Stevens & McCoy to have negligently failed to warn plaintiffs of harmful beryllium exposures, it must have undertaken the responsibility of making that warning.”).

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<sup>28</sup> The Second Restatement of Torts § 324A outlines the tort of negligent undertaking when the harm is suffered by a third party. Restatement (Second) of Torts § 324A (Liability to Third Person for Negligent Performance of Undertaking); *see also id.* cmt. a (discussing differences between § 323 and § 324A). Plaintiffs concede that “the facts here more appropriately fall within § 323 because the person who saw the direct-to-consumer advertisement and sought a prescription on that basis is also the person who was harmed.” (Doc. No. 364 at 55 n.21.)

Defendants argue that Plaintiffs’ allegations are nevertheless insufficient here because under the learned intermediary doctrine, “non-physicians such as pharmacists and drug manufacturers do not have an independent duty to warn about the dangers and side-effects of prescription drugs.” *Slater v. Hoffman-La Roche Inc.*, 771 F. Supp. 2d 524, 527–28 (E.D. Pa. 2011). Defendants assert that Plaintiffs’ negligent undertaking claim is an unsuccessful attempt to plead around this doctrine. (Doc. No. 329-1 at 41.) But at least some courts have found the learned intermediary doctrine inapplicable when the plaintiff alleges that the defendant “voluntarily assume[d] a duty that would not otherwise be imposed on it.” *Cottman*, 764 N.E.2d at 820–22 (extending application of the learned intermediary doctrine to pharmacies but nevertheless finding the plaintiff could pursue negligent undertaking claim where the pharmacy “provided him with a list of side effects of Trazodone” that was incomplete); *see also Slater*, 771 F. Supp. 2d at 527–28 (rejecting the defendant’s argument that a [patient education monograph] publisher was shielded by the learned intermediary doctrine because the plaintiff did “not argue that WKH had an independent duty to warn,” but rather, that “WKH voluntarily assumed a duty to exercise due care in issuing drug warnings by providing written drug information and warnings directed to patient end-users”); *Kasin v. Osco Drug, Inc.*, 728 N.E.2d 346, 349 (Ill. App. Ct. 2000) (reading Illinois Supreme Court opinion to “impl[y] that the learned intermediary doctrine does not apply once a pharmacist voluntarily undertakes to warn a consumer of a drug’s dangerous propensities”); *cf. Perez v. Wyeth Labs., Inc.*, 734 A.3d 1245 (N.J. 1999) (holding that “the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers”).<sup>29</sup>

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<sup>29</sup> Defendants latch on to the Master Complaint’s reference to *Perez*, arguing the New Jersey court’s opinion is inapplicable because it “did not evaluate voluntary undertaking arguments.” (Doc. No. 329-1 at 42.) But a review of *Perez* shows that, similar to the courts in *Cottman*, *Slater*, and *Kasin*, the

Given these holdings, the Court declines to dismiss Plaintiffs’ negligent undertaking claim at this stage. Whether an individual Plaintiff will be able to show (1) that the applicable state recognizes such a claim in this context,<sup>30</sup> (2) if so, that the advertisements on which they relied negligently failed to disclose the risks of taking a given GLP-1 RA, and (3) that the plaintiff sought a prescription because of a specific advertisement, are fact-dependent issues that are best addressed later in this litigation.

Accordingly, the Court denies Defendants’ motion as to Count XIV.

#### 7. Statutory Claims

Seventh, Defendants argue that Plaintiffs have failed to identify their statutory claims with the requisite specificity. The Master Complaint identifies two categories of statutory claims; the first category includes claims brought pursuant to state unfair practice and consumer protection laws (“UPLs”), and the second category relates to claims brought pursuant to state product liability acts (“PLAs”). The Master Complaint proposes different processes for individual plaintiffs to assert each type of claim. The UPL claims are encompassed in a single count, Count VII, which broadly references each state statute in its entirety, without identifying the specific subsections on which Plaintiffs base their claims. The PLA claims, by contrast, are

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court considered, “whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product’s safety.” *Perez*, 734 A.3d at 1257.

<sup>30</sup> Notably, Defendants argue that “*Perez* is an outlier opinion that many other state courts have declined to follow” (Doc. No. 329-1 at 41–42 (discussing Texas law)), and that outside of any discussion of *Perez*, “some state courts have rejected the application of negligent undertaking in product liability cases absent unique facts that are not pleaded here.” (*Id.* at 43 (citing cases discussing the laws of Pennsylvania, Nevada, Michigan)). They also argue that even if a plaintiff wants to “apply New Jersey law” and rely on *Perez*, they would have to run into New Jersey’s [Product Liability Act] requirements,” which “create a presumption that the FDA label is appropriate.” (Apr. 21, 2025 Hr’g Tr. at 30:9–12.) As before, the Court declines to consider distinctions in state law at this early stage.



not identified in a single count, but instead, are left to be addressed solely through the short form complaint process.

The Court addresses each category in turn.

*a. UPLs*

Beginning with the UPLs, Defendants note that Count VII references, without context, the statutes of 55 states and territories. (Doc. No. 329-1 at 32–35.) Defendants argue that by pleading the UPL claims in this manner, Plaintiffs erroneously “leave for the Court and Defendants to guess what unfair trade practices claims they are asserting.” (*Id.* at 32.) Defendants also note that there is “substantial variation” among the various state UPLs, and that for efficiency, Plaintiffs should be required to precisely identify the specific subsections of each state’s UPL on which their claims are based and for which they have provided supporting factual allegations. (Apr. 21, 2025 Hr’g Tr. at 37:14–38:14.)<sup>31</sup>

Plaintiffs respond that in the Master Complaint, they include “the core allegations and . . . identify the activities that [they] think are—would be qualified as fraudulent, unfair and deceptive” under the UPLs, such that the “only thing that would happen by breaking this out into a bunch of counts is you would add 50 counts to” the Master Complaint. (Apr. 21, 2025 Hr’g Tr. at 65:23–66:3.) But that’s not entirely true. Notably, “breaking [Count VII] out” now means Plaintiffs will be required to identify specifically which statutes and, more importantly, the subsections of those statutes, on which they base their claims. (*See id.* at 65:10–12 (acknowledging that as currently pleaded, Count VII “cite[s] the first provision of the statute, *et*

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<sup>31</sup> Defendants also argue that Count VII should be dismissed because the Master Complaint “fails to satisfy many, if not all, of the statutes they cite.” (Doc. No. 329-1 at 33.) Defendants then discuss certain limitations imposed by Alabama, New Jersey, West Virginia, Florida, Alaska, Hawaii, Iowa, Maine, Oregon, Washington, and Texas courts. (*Id.* at 33–35.) As the Court noted earlier in this Memorandum, however, state-specific issues are not being considered at this stage of the proceedings.

*seq.*, meaning the entire statute”).) And although Plaintiffs repeatedly stated that Defendants are “on notice of what we’re claiming [t]hat’s deceptive, fraudulent and unfair,” they never specifically identify which allegations form the basis of Count VII. (*See, e.g., id.* at 66:10–12.)

The Court agrees with Defendants that Plaintiffs must provide greater specificity as to the factual and legal bases for their UPL claims. The Court will not, however, mandate that Plaintiffs provide that specificity in an amended master complaint. Instead, Plaintiffs may choose whether to amend the Master Complaint or to provide this information during the short form complaint process. To the extent Plaintiffs wish to assert UPL claims on a master basis, they must: (1) identify the specific subsections of each jurisdiction’s statute on which their claims are based, and (2) provide some indication of the factual theory supporting their reliance on each subsection. In the alternative, Plaintiffs may leave these claims to be asserted with greater specificity by individual Plaintiffs through the short form complaint process.<sup>32</sup> Should Plaintiffs choose this latter route, then they are warned that any Plaintiff who asserts such a claim in their short form complaint *must* state the claim with the factual and legal specificity identified in this paragraph, or risk having their short form complaint stricken.<sup>33</sup>

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<sup>32</sup> The Court encourages Plaintiffs’ Co-Lead Counsel to give due consideration to pleading these claims on a master basis. Tellingly, during oral argument, Plaintiffs’ counsel stated, “I think what’s going to happen is [in] the short-form complaint people are going to check off their state statute. . . . I don’t think people are even going to have a lot of facts.” (Apr. 21, 2025 Hr’g Tr. at 66:19–25, 90:25–92:18.) If Plaintiffs’ Co-Lead Counsel truly believe that the short form complaint process will not lead to any greater clarity, then it makes no sense to wait to assert the UPL claims at that time.

<sup>33</sup> If Plaintiffs elect this path, the amended master complaint should continue to include a stand-alone count for UPL claims, and the parties’ proposed short form complaint should: (1) provide a space for each Plaintiff to indicate the specific statute (including subsections) under which they are bringing UPL claims and the factual allegations supporting those claims, and (2) include a notice that warns every Plaintiff that failure to identify the UPL claims with the requisite specificity will result in the short form complaint being stricken with only one opportunity to amend.

*b. PLAs*

Defendants argue that Plaintiffs should also be required to specifically plead claims being brought under state PLAs. (Doc. No. 329-1 at 13.) Unlike the UPL claims, the PLAs are not assigned a standalone count in the Master Complaint, nor is any state’s PLA specifically referenced in the Master Complaint. Instead, throughout the Master Complaint, Plaintiffs state in general fashion that they “intend to plead all claims of product liability that are supported by their factual allegations and that exist under the statutes and common law of the state or states applicable to their claims, including any applicable state Product Liability Act.” (*See, e.g.*, Doc. No. 294 at ¶ 647.)

After the motion to dismiss was filed, the parties submitted a proposed short form complaint for the Court’s approval. Paragraphs 20 and 21 of that proposed short form complaint direct each Plaintiff to indicate whether “any state Product Liability Act or other statute(s) define the parameters of any or all [of their] claim(s),” identify the common law claims subsumed by the statute or rule, and confirm that they provided the requisite pre-suit notice to Defendant(s). (Doc. No. 387-2 at 8.) Although this seems to address Defendants’ concerns, during oral argument, Defendants maintained their position that the Court should require Plaintiffs to identify the relevant PLAs, including subsections, in the Master Complaint because it will allow the Court to more efficiently address motions to dismiss directed to state-specific issues. (*See* Apr. 21, 2025 Hr’g Tr. at 112:20–24 (“It’s our assertion that the plaintiffs should do more of that work now, and that by doing that work up front we will save everyone time and effort on the back end, and that we don’t just defer those issues to later on.”).)

As with the state UPL claims, the Court leaves to Plaintiffs whether to plead the PLA claims on a master basis or through the short form complaint process. If Plaintiffs choose to

plead the PLA claims on a master basis, the amended master complaint must: (1) include a standalone PLA count, (2) identify the PLAs on which their claims are based, including relevant subsections, and (3) provide some indication of the factual theory supporting their reliance on each PLA. In the alternative, Plaintiffs may leave these claims to be asserted with greater specificity by individual Plaintiffs through the short form complaint process.<sup>34</sup> Should Plaintiffs choose this latter route, then they are warned that any Plaintiff who asserts such a claim in their short form complaint *must* state the claim with the factual and legal specificity identified in this paragraph, or risk having their short form complaint stricken.<sup>35</sup> Regardless of which path Plaintiffs' Co-Lead Counsel choose, all Plaintiffs' counsel are also warned that to the extent they intend to assert a PLA claim, they should consider whether the applicable state's law forecloses their ability to assert common law claims. *See supra* n.15.

#### 8. Medical Monitoring Relief

Last, Defendants argue that Plaintiffs' request for medical monitoring should be dismissed because their request is "speculative and threadbare, falling far short of the standard for compensable injury applied by state courts." (Doc. No. 329-1 at 46–47.) "Medical monitoring claims are non-traditional torts, through which individuals 'seek to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may

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<sup>34</sup> Again, the Court encourages Plaintiffs' Co-Lead Counsel to give due consideration to pleading these claims on a master basis. Tellingly, during oral argument, Plaintiffs' counsel stated, "I think what's going to happen is [in] the short-form complaint people are going to check off their state statute. . . . I don't think people are even going to have a lot of facts." (Apr. 21, 2025 Hr'g. Tr. at 66:19–25, 90:25–92:18.) If Plaintiffs' Co-Lead Counsel truly believe that the short form complaint process will not lead to any greater clarity, then it makes no sense to wait to assert the PLA claims at that time.

<sup>35</sup> If Plaintiffs elect this path, the amended master complaint should nevertheless add a stand-alone count for PLA claims, and the parties' proposed short form complaint should: (1) provide a space for each Plaintiff to indicate the specific statute (including subsections) under which they are bringing PLA claims and the factual allegations supporting those claims, and (2) include a notice that warns every Plaintiff that failure to identify the PLA claims with the requisite specificity will result in the short form complaint being stricken with only one opportunity to amend.

develop as a result of tortious exposure.” *In re Zantac (Ranitidine) Prods. Liab. Litig.* (“*In re Zantac*”), 546 F. Supp. 3d 1152, 1169 (S.D. Fla. 2021) (quoting *In re NHL*, 327 F.R.D. 245, 259–60 (D. Minn. 2018)). Whether framed as an independent claim or a form of relief, a request for medical monitoring is meant to “allow plaintiffs some relief even absent present manifestations of physical injury” by compensating them for the “quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm.” *In re Paoli R.R. Yard PCB Litig.*, 916 F. 2d 829, 850 (3d Cir. 1990); *see also id.* (framing it as a question of “whether the plaintiff needs medical surveillance”).

As other MDL courts have recognized, the “law of medical monitoring varies across jurisdictions, with some requiring a showing of manifest physical injury, some requiring subcellular or subclinical injury, and others not requiring any present physical injury. *In re Zantac*, 546 F. Supp. 3d at 1169. Similarly, “some states require that testing procedures exist to detect diseases early, while others do not,” and still others require “a significant exposure” to a toxic substance “as an express element of the medical monitoring claim,” while in others, “the requirement for a significant exposure exists in the form of a reasonable treating physician’s diagnosis.” *Id.* at 1169–70 (collecting cases); *see also In re Respironics Recalled CPAP, BI-Level PAP, & Mechanical Ventilator Prods. Litig.*, Master Docket: Misc. No. 21-1230, MDL No. 3014, 2024 WL 626100, at \*3 (W.D. Pa. Feb. 14, 2024) (“The elements to obtain medical monitoring differ among states. . . . [S]ome states require a plaintiff to show the existence of physical harm; other states do not. . . . Some states require that manifest personal injury be alleged. Some states require proof of an increased risk of future injury; other states require proof of a ‘significantly’ increased risk of future injury. Some states require that treatment for the plaintiff’s ailment exist; other states have expressly eliminated that requirement.”).

Once again, the Court declines to parse out the variations in state law at this stage of the litigation. Nevertheless, the Court finds that, regardless of the jurisdiction, Plaintiffs have failed to adequately plead facts to support their request for medical monitoring. In the Master Complaint's prayer for relief, Plaintiffs request "medical monitoring to diagnose GLP-1 RA induced injuries at an earlier date to allow for timely treatment and prevention of exacerbation of injuries." (Doc. No. 294 at 243.) But nowhere do they specify for which "injuries" they seek monitoring, identify the relevant tests, or explain how those tests would ensure "timely treatment and prevention." (*Id.*) Plaintiffs' response brief similarly states in conclusory fashion that "it is proper to seek compensation for any medical monitoring they require to prevent exacerbation of their injuries or additional injuries resulting from their use of Defendants' GLP-1 RAs." (Doc. No. 364 at 61.) But again, they do not identify which injuries they are hoping to prevent or how monitoring would prevent them.

Without more, the Court agrees with Defendants that Plaintiffs' request seeks nothing more than an "award for . . . speculative, unspecified future medical tests." (Doc. No. 329-1 at 47.) Indeed, during oral argument, Plaintiffs' counsel essentially conceded their request for medical monitoring expenses was coextensive with their request for future medical expenses. (*See* Apr. 21, 2025 Hr'g Tr. at 98:17–22 ("We are just bringing it as a remedy for an injury that already exists. . . . It's just like future medical expenses."); *id.* at 99:9–10 ("[I]t's just medical expenses, really. With a different name.")) Accordingly, the request for medical monitoring is dismissed. *See In re Zantac*, 546 F. Supp. 3d at 1170–79 (dismissing medical monitoring claim where the plaintiffs failed to plausibly allege that exposure to the toxic substance resulted in a "substantial increase in the risk of cancer," that "diagnostic tests exist for early detection of the Subject Cancers" or that "their proposed monitoring regime differs from what is normally

recommended absent exposure”); *In re Avandia*, 2011 WL 4006639, at \*3 (“The claim for medical monitoring essentially tracks the elements of the claim, but without any specific facts alleged (e.g., as to what medical monitoring procedure exists and how it differs from the monitoring for all patients with Type 2 diabetes).”). Plaintiffs are, however, given leave to amend if they can, in good faith, plead a claim for medical monitoring (as opposed to future medical expenses) with the requisite specificity.

## **VI. CONCLUSION**

In sum, Defendants’ request for judicial notice (Doc. No. 328) and motion to strike (Doc. No. 329-1 at 47–49) are denied. Defendants’ motion to dismiss (Doc. No. 329) is denied in part and granted in part. The motion is denied to the extent it seeks dismissal of Counts III, IV, and XIV. The motion is granted with leave to amend as to Counts VI, VII, XI, XII, XIII, Plaintiffs’ PLA claims, and Plaintiffs’ request for medical monitoring. As to Count V, the motion is denied to the extent Plaintiffs allege fraudulent omission of information about the Alleged Injuries in the GLP-1 RAs’ FDA-approved labels; it is granted with leave to amend to the extent Plaintiffs allege Defendants failed to disclose information about the Alleged Injuries outside of the labels and failed to disclose the inadequacy of testing. As to Counts VIII through X, the motion is denied to the extent Plaintiffs’ claims are based on misrepresentations to consumers about the medications’ weight loss benefits and misrepresentations in the drugs’ labels about the risks associated with taking the medications; the motion is granted to the extent these claims are based on unidentified communications to physicians, consumers, and the medical community about the drugs’ weight loss benefits or the medications’ safety (to the extent the communications were made outside of the labels). An appropriate order follows.